PUBLIC

THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of **Illumina, Inc.,** **a corporation,** **and** **GRAIL, Inc.,** **a corporation.**	**DOCKET NO. 9401**

COMPLAINT COUNSEL'S POST-TRIAL REPLY PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. INTRODUCTION

A. Illumina

1. Overview

1. Illumina is the global leader in sequencing- and array-based solutions for genetic and genomic analysis. (PX0061 (Illumina) at 5; PX0091 (Illumina) at 4.) Illumina's focus is on next-generation sequencing ("NGS") technology. NGS technology is a much higher throughput type of sequencing that allows for the simultaneous sequencing of millions or even billions of sequences in a single run. (Aravanis (Illumina) Tr. 1841.)

Response to Finding No. 1

Complaint Counsel does not disagree that Illumina is the dominant provider of NGS instruments and consumables, and indeed the only option feasible for MCED test developers. (*See* CCFF ¶¶ 1019-1211). In fact, Illumina is the only provider of NGS systems in the United States that is capable of "simultaneous sequencing of … billions of sequences in a single run" (PX0085 (Illumina) at 001, 003 (NovaSeq 6000 System Specifications (stating that the NovaSeq can generate 20 billion single-end reads per run using two S4 flow cells)), which is a key technical requirement for MCED testing (*see* CCFF ¶¶ 931-54).

Complaint Counsel also does not agree that NGS offers "much higher throughput" than other types of sequencing.

2. Illumina was incorporated in California in April 1998 and reincorporated in Delaware in July 2000. (PX0061 (Illumina) at 5.) Its principal executive offices are located in San Diego, California. (PX0061 (Illumina) at 5.)

Response to Finding No. 2

Complaint Counsel does not disagree with the proposed finding.

3. Illumina's products and services serve customers in a wide range of markets, enabling the adoption of genomic solutions in research and clinical settings. (PX0061 (Illumina) at 5; *see also* Berry (Illumina) Tr. 807–08.) Illumina's customers include leading genomic research centers, academic institutions, government laboratories, and hospitals, as well as pharmaceutineecal, biotechnology, commercial molecular diagnostic laboratories, and consumer

genomics companies. (PX0061 (Illumina) at 5; *see also* deSouza (Illumina) Tr. 2313–15; Berry (Illumina) Tr. 807–09; [redacted]

Response to Finding No. 3

Complaint Counsel has no specific response.

4. Illumina's portfolio of integrated sequencing and microarray systems, consumables, and analysis tools is designed to accelerate and simplify genetic analysis. (PX0061 (Illumina) at 5.) This portfolio addresses the range of genomic complexity, price points, and throughput, enabling customers to select the best solution for their research or clinical application. (PX0061 (Illumina) at 5; PX0091 (Illumina) at 14.)

Response to Finding No. 4

Complaint Counsel has no specific response.

2. **Illumina's Businesses**

5. Illumina targets life sciences and clinical genomics segments and customers. (PX0061 (Illumina) at 6; deSouza (Illumina) Tr. 2318.)

Response to Finding No. 5

Complaint Counsel has no specific response.

6. Life Sciences. Historically, Illumina's core business has been in life sciences research. (PX0061 (Illumina) at 6.)

Response to Finding No. 6

Complaint Counsel has no specific response.

6.1 This includes laboratories associated with universities, research centers, and government institutions, along with biotechnology and pharmaceutical companies. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2312–13; [redacted]

Response to Finding No. 6.1

Complaint Counsel has no specific response.

6.2 Researchers at these institutions use Illumina's products and services for basic and translational research across a spectrum of scientific applications, including targeted, exome, and whole-genome sequencing, genetic variation; gene expression, epigenetics, and metagenomics. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2313–15; [redacted]

Response to Finding No. 6.2

Complaint Counsel has no specific response.

6.3 Next-generation sequencing (NGS) technologies are being adopted due to their ability to sequence large sample sizes quickly, accurately, and cost-effectively, generating vast amounts of high-quality data. (PX0061 (Illumina) at 6.)

Response to Finding No. 6.3

Complaint Counsel has no specific response.

7. Illumina's products also serve various applied markets including consumer genomics and agrigenomics. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2318.)

Response to Finding No. 7

Complaint Counsel has no specific response.

7.1 For example, in consumer genomics, Illumina's customers use Illumina's technologies to provide personalized genetic data and analysis to individual consumers. (PX0061 (Illumina) at 6; PX0091 (Illumina) at 24.)

Response to Finding No. 7.1

Complaint Counsel has no specific response.

7.2 In agrigenomics, government and corporate researchers use Illumina's products and services to explore the genetic and biological basis for productivity and nutritional constitution in crops and livestock. (PX0061 (Illumina) at 6; *see also* Berry (Illumina) Tr. 807.) Researchers can identify natural and novel genomic variation and deploy genome-wide, marker-based applications to accelerate breeding and production of healthier and higher-yielding crops and livestock. (PX0061 (Illumina) at 6.)

Response to Finding No. 7.2

Complaint Counsel has no specific response.

8. Clinical Genomics. Illumina is focused on enabling translational and clinical markets through the introduction of best-in-class sequencing technology. (PX0061 (Illumina) at 6; *see also* [redacted]; PX0091 (Illumina) at 18.) Further, Illumina is developing sample-to-answer solutions to catalyze adoption in the clinical setting, including in reproductive and genetic health and oncology. (PX0061 (Illumina) at 6; *see also* PX7072 (deSouza (Illumina) IHT at 157–58).)

Response to Finding No. 8

[redacted]

9. *Reproductive Health.* In reproductive health, Illumina's primary focus is driving the adoption of noninvasive prenatal testing (NIPT) globally through Illumina's technology, which identifies fetal chromosomal abnormalities by analyzing cell-free DNA in maternal blood. (PX0061 (Illumina) at 6; RX2264 (Illumina) at 50); PX0091 (Illumina) at 20–21.)

Response to Finding No. 9

Complaint Counsel has no specific response to this proposed finding.

10. *Rare and Undiagnosed Disease.* Illumina's NGS technology is also accelerating rare and undiagnosed disease research to discover the genetic causes of inherited disorders by assessing many genes simultaneously. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2326–27, PX0091 (Illumina) at 22.) Using NGS can reduce costs compared to traditional methods of disease diagnosis, which are often expensive and inconclusive while requiring extensive testing. (PX0061 (Illumina) at 6.)

Response to Finding No. 10

Complaint Counsel has no specific response to this proposed finding.

11. *Oncology.* Cancer is a disease of the genome, and the goal of cancer genomics is to identify genomic changes that transform a normal cell into a cancerous one. (PX0061 (Illumina) at 6.) Understanding these genomic changes will improve diagnostic accuracy, increase understanding of the prognosis, and enable oncologists to target therapies to individuals. (PX0061 (Illumina) at 6; *see also* Aravanis (Illumina) Tr. 1828.)

Response to Finding No. 11

Complaint Counsel has no specific response to this proposed finding.

11.1 There are a variety of NGS applications in oncology including: research applications where people sequence cancer cells to understand cancer biology, how cancer is behaving and how to treat it; therapy selection applications where a tumor is sequenced to understand whether or not any of the mutations that are present might be targetable by a drug, monitoring or minimal residual disease where the goal is to look for cancer signals in the blood in order to determine how effective a treatment is and early cancer detection where cancer is detected in asymptomatic patients. (Aravanis (Illumina) Tr. 1843.)

Response to Finding No. 11.1

Complaint Counsel has no specific response to this proposed finding.

11.2 Customers in the translational and clinical oncology markets use Illumina's products to perform research that may help identify individuals who are genetically predisposed to cancer and to identify molecular changes in a tumor. (PX0061 (Illumina) at 6; *see also* Berry (Illumina) Tr. 814–22; PX0091 (Illumina) at 17; [redacted] Illumina believes that circulating tumor DNA (ctDNA) will become an important clinical tool for managing oncology patients during all stages of tumor progression. (PX0061 (Illumina) at 6–7; [redacted]

Response to Finding No. 11.2

[redacted]

11.3 Illumina's technology is being used to research the implications of ctDNA in treatment determination, treatment monitoring, minimal residual disease, and asymptomatic screening. (PX0061 (Illumina) at 7; *see also* Aravanis (Illumina) Tr. 1843; PX0091 (Illumina) at 19.)

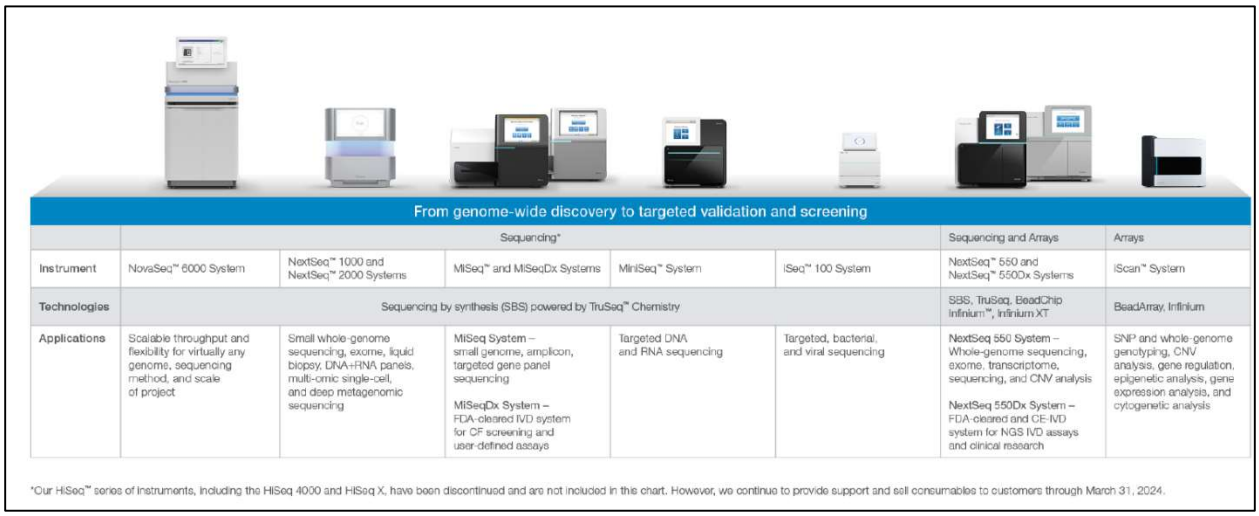
Response to Finding No. 11.3

Complaint Counsel has no specific response to this proposed finding.

3. **Principal Products, Services and Technologies**

12. Illumina's unique technology platforms support the scale of experimentation necessary for population-scale studies, genome-wide discovery, target selection, and validation studies. (PX0061 (Illumina) at 7; Berry (Illumina) Tr. 823–26.)

Figure 1: Illumina Platform Overview



From genome-wide discovery to targeted validation and screening

	Sequencing*					Sequencing and Arrays	Arrays
Instrument	NovaSeq™ 6000 System	NextSeq™ 1000 and NextSeq™ 2000 Systems	MiSeq™ and MiSeqDx Systems	MiniSeq™ System	iSeq™ 100 System	NextSeq™ 550 and NextSeq™ 550Dx Systems	iScan™ System
Technologies	Sequencing by synthesis (SBS) powered by TruSeq™ Chemistry					SBS, TruSeq, BeadChip Infinium™, Infinium XT	BeadArray, Infinium
Applications	Scalable throughput and flexibility for virtually any genome, sequencing method, and scale of project	Small whole-genome sequencing, exome, liquid biopsy, DNA+RNA panels, multi-omic single-cell, and deep metagenomic sequencing	MiSeq System – small genome, amplicon, targeted gene panel sequencing MiSeqDx System – FDA-cleared IVD system for CF screening and user-defined assays	Targeted DNA and RNA sequencing	Targeted, bacterial, and viral sequencing	NextSeq 550 System – Whole-genome sequencing, exome, transcriptome, sequencing, and CNV analysis NextSeq 550Dx System – FDA-cleared and CE-IVD system for NGS IVD assays and clinical research	SNP and whole-genome genotyping, CNV analysis, gene regulation, epigenetic analysis, gene expression analysis, and cytogenetic analysis

*Our HiSeq™ series of instruments, including the HiSeq 4000 and HiSeq X, have been discontinued and are not included in this chart. However, we continue to provide support and sell consumables to customers through March 31, 2024.

Response to Finding No. 12

The proposed finding is vague and confusing. The proposed finding is vague because the term "support" is ambiguous and undefined. The proposed finding is also vague because the phrases "scale of experimentation," "population-scale studies," "genome-wide discovery," "target selection," and "validation studies" are ambiguous and undefined. The proposed finding is also vague because it references Illumina's "technology platforms" generically and does not specify which specific platform or platforms "support" particular listed attributes. The proposed finding is confusing because the relevance of the ambiguous attributes to MCED development is not specified.

Respondents' inclusion of Figure 1 in the proposed finding is itself confusing. Complaint Counsel is unsure for what purpose Figure 1 is offered. Given that Respondents do not specifically reference the figure or state whether it is offered for the truth, for the fact that particular statements were made, or for some other purpose, the material is not properly offered

as a finding of fact and should be disregarded. To the extent Respondents purport to simply include everything within Figure 1 as a "fact," the proposed finding is improper because it would represent a compound finding rather than a single finding of fact. To the extent anything in the proposed finding is intended to suggest that Illumina NGS sequencing is not a necessary input to MCED tests, the proposed finding is also misleading and against the weight of the evidence. (*See* CCFF ¶¶ 886- 1900).

13. Customers use Illumina's products to analyze the genome at all levels of complexity, from targeted panels to whole-genome sequencing. (PX0061 (Illumina) at 7.) A large and dynamic Illumina user community has published tens of thousands of customer-authored scientific papers using Illumina's technologies. (PX0061 (Illumina) at 7.) Through rapid innovation, Illumina is changing the economics of genetic research, enabling projects that were previously considered impossible, and supporting clinical advances towards precision medicine. (PX0061 (Illumina) at 7.)

Response to Finding No. 13

The proposed finding is vague because Respondents do not explain how Illumina is "changing the economics of genetic research" or identify which projects Illumina is enabling "that were previously considered impossible." Moreover, Respondents proposed finding is misleading to the extent that it implies Illumina is not profiting off of the sale its sequencers to the "larger and dynamic Illumina user community." Therefore, this Court should disregard the proposed finding.

14. Most of Illumina's product sales consist of instruments and consumables, which include reagents, flow cells, and microarrays, based on Illumina's proprietary technologies. (PX0061 (Illumina) at 7; *see also* Aravanis (Illumina) Tr. 1844–47; Berry (Illumina) Tr. 826–28.)

Response to Finding No. 14

Complaint Counsel has no specific response to this proposed finding.

15. Illumina also performs various services for its customers. (PX0061 (Illumina) at 7; *see also* [redacted], 865–66; PX7076 (Berry (Illumina) Dep. at 87–92); PX7063 (Berry (Illumina) IHT at 35–36.) In 2020, 2019, and 2018, instrument sales represented 13%, 15%, and 17%, respectively, of total revenue; consumable sales represented 71%, 68%,

and 65%, respectively, of total revenue; and services represented 16%, 17%, and 18%, respectively, of total revenue. (PX0061 (Illumina) at 7.)

Response to Finding No. 15

[redacted]

16. Sequencing. DNA sequencing is the process of determining the order of nucleotide bases (A, C, G, or T) in a DNA sample. (PX0061 (Illumina) at 7; *see also* Aravanis (Illumina) Tr. 1828.)

Response to Finding No. 16

Complaint Counsel does not disagree with the proposed finding.

16.1 Illumina's portfolio of sequencing platforms represents a family of systems that Illumina believes set the standard for productivity, cost-effectiveness, and accuracy among NGS technologies. (PX0061 (Illumina) at 7; deSouza (Illumina) Tr. 2327–2328; Berry (Illumina) Tr. 809–811.)

Response to Finding No. 16.1

The proposed finding is vague because it does not define what the "standard for productivity, cost-effectiveness, and accuracy among NGS technologies" is. Therefore, this Court should disregard the proposed finding.

17. Customers use Illumina's platforms to perform whole-genome, de novo, exome and RNA sequencing, as well as targeted resequencing of specific gene regions and genes. (PX0061 (Illumina) at 7.)

Response to Finding No. 17

The proposed finding is misleading because customers using Illumina NGS instruments for MCED testing—which is at issue in this proceeding—do not use Illumina's platform for whole-genome sequencing, de novo sequencing, or exome sequencing, nor do they use Illumina platforms for targeted resequencing (as that term is typically employed, referring to sequencing genomic or chromosomal DNA from sources such as white blood cells). MCED developers use

Illumina's NGS platform to simultaneously examine thousands of cancer biomarkers in cfDNA extracted from blood plasma samples. (*See* CCFF ¶¶ 340-48). Therefore, this Court should disregard the proposed finding.

17.1 Whole-genome sequencing determines the complete DNA sequence of an organism. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 76.)

Response to Finding No. 17.1

The proposed finding is misleading because customers using Illumina NGS instruments for MCED testing—which is at issue in this proceeding—do not use Illumina's platform for whole-genome sequencing. MCED developers use Illumina's NGS platform to simultaneously examine thousands of cancer biomarkers in cfDNA extracted from blood plasma samples. (*See* CCFF ¶¶ 340-48). Therefore, this Court should disregard the proposed finding.

17.2 In de novo sequencing, the goal is to sequence and assemble the genome of that sample without using information from prior sequencing of that species. (PX0061 (Illumina) at 7.)

Response to Finding No. 17.2

The proposed finding is misleading because customers using Illumina NGS instruments for MCED testing—which is at issue in this proceeding—do not use Illumina's platform for de novo sequencing. MCED developers use Illumina's NGS platform to simultaneously examine thousands of cancer biomarkers in cfDNA extracted from blood plasma samples. (*See* CCFF ¶¶ 340-48). Therefore, this Court should disregard the proposed finding.

17.3 In targeted resequencing, a portion of the sequence of an organism is compared to a standard or reference sequence from previously sequenced samples to identify genetic variation. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 74.)

Response to Finding No. 17.3

The proposed finding is misleading because customers using Illumina NGS instruments for MCED testing—which is at issue in this proceeding—do not use Illumina's platform for

targeted resequencing (as that term is typically employed, referring to sequencing genomic or chromosomal DNA from sources such as white blood cells). MCED developers use Illumina's NGS platform to simultaneously examine thousands of cancer biomarkers in cfDNA extracted from blood plasma samples. (*See* CCFF ¶¶ 340-48). Therefore, this Court should disregard the proposed finding.

18. Illumina's DNA sequencing technology is based on its proprietary reversible terminator-based sequencing chemistry, referred to as sequencing by synthesis (SBS) biochemistry. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 154)

Response to Finding No. 18

Complaint Counsel has no specific response to the proposed finding.

18.1 SBS tracks the addition of labeled nucleotides as the DNA chain is copied in a massively parallel fashion. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 154.)

Response to Finding No. 18.1

The proposed finding is vague in its use of the phrase "in a massively parallel fashion." The Illumina NovaSeq can read 20 billion DNA fragments simultaneously in a single run of the instrument. (PX0085 at 001, 003 (Illumina NovaSeq 6000 System Specifications (stating that the NovaSeq can generate 20 billion single-end reads per run using two S4 flow cells)). Therefore, this Court should disregard the proposed finding.

18.2 Illumina's SBS sequencing technology provides researchers with a broad range of applications and the ability to sequence even large mammalian genomes in a few days rather than weeks or years. (PX0061 (Illumina) at 7–8; *cf.* RX2264 (Illumina) at 156.)

Response to Finding No. 18.2

The proposed finding is vague because it does not identify the "broad range of applications" referenced. The proposed finding is misleading because customers using Illumina NGS instruments for MCED testing—which is at issue in this proceeding—do not use Illumina's platform for sequencing large mammalian genomes. MCED developers use Illumina's NGS

platform to simultaneously examine thousands of cancer biomarkers in cfDNA extracted from blood plasma samples. (*See* CCFF ¶¶ 340-48). Therefore, this Court should disregard the proposed finding.

19. Illumina's sequencing platforms can generate between 500 megabases (Mb) and 6.0 terabases (Tb) (equivalent to approximately 48 human genomes) of genomic data in a single run, depending on the instrument and application. (PX0061 (Illumina) at 8; *see also* Aravanis (Illumina) Tr. 1841.)

Response to Finding No. 19

The proposed finding is misleading because it employs the metric of bases (i.e., megabases, gigabases, or terabases) per sequencing run, which is irrelevant when utilizing NGS for liquid biopsy applications such as MCED testing, which is at issue in this case. The total output in bases of a sequencer per run of the instrument (or per period of time) is an irrelevant metric for the application of MCED tests. [redacted] Therefore, this Court should disregard the proposed finding.

20. There are different price points per gigabase (Gb) for each instrument, and for different applications, which range from small-genome, amplicon, and targeted gene-panel sequencing to population-scale whole human genome sequencing. (PX0061 (Illumina) at 8; *see also* [redacted]

Response to Finding No. 20

[redacted]

[redacted]

21. Since Illumina launched its first sequencing system in 2007, its systems have reduced the cost of sequencing by a factor of more than 10,000. In addition, the sequencing time per Gb has dropped by a factor of approximately 12,000. (PX0061 (Illumina) at 8, 14.)

Response to Finding No. 21

Complaint Counsel has no specific response to the proposed finding.

22. In 2018, 2019, and 2020, total sequencing revenue comprised 83%, 87%, and 89%, respectively, of total revenue. (PX0061 (Illumina) at 8; *see also* PX0091 (Illumina) at 11.)

Response to Finding No. 22

The proposed finding is vague because it does not define "sequencing revenue." The proposed finding is misleading to the extent it suggests that post merger Illumina will not have the incentive to foreclose access or raise costs of Illumina NGS to GRAIL's MCED rivals in order to hurt their competitiveness and cause them to lose sales to GRAIL. [redacted] Therefore, this Court should disregard the proposed finding.

23. [redacted]

Response to Finding No. 23

[redacted]

24. Arrays. Arrays are used for a broad range of DNA and RNA analysis applications, including SNP genotyping, CNV analysis, gene expression analysis, and methylation analysis, and enable the detection of millions of known genetic markers on a single array. (PX0091 (Illumina) at 15; *see also* PX7072 (deSouza (Illumina) IHT at 55).)

Response to Finding No. 24

The proposed finding is vague and misleading. It is vague because it does not define "SNP genotyping," "CNV analysis," "gene expression analysis," and "methylation analysis," with any specificity. It is misleading because microarray technologies test DNA fragments for the presence of predefined target sequences. (CCFF ¶ 1407). To say that microarrays "enable the detection of millions of known genetic markers on a single array," is to obfuscate that, in fact, microarrays determine whether specific sequences are present within a sample, and they do not provide precise readouts of the sequence of nucleotides contained within fragments of DNA. (*See* CCFF ¶ 1410; *see also* PX7070 (Felton (Thermo Fisher) IHT at 20-21) ("The microarray technology provides for…hypothesis-based experiments primarily for gene expression, genotyping, and copy. By that we mean, you have to know something about the sequences that you're trying to interrogate to place them onto the array to be detected; whereas, next-generation sequencing is a so-called hypothesis-free technology in which you do not have to understand the sequences that you are trying to interrogate. You just sequence them directly.")). [redacted] Therefore, this Court should disregard the proposed finding.

24.1 Arrays are the primary technology used in consumer genomics applications. (PX0061 (Illumina) at 8; *see also* PX7076 (Berry (Illumina) Dep. at 158); *cf.* Berry (Illumina) Tr. 805.)

Response to Finding No. 24.1

[redacted]

[redacted]

24.2 Illumina's BeadArray technology combines microscopic beads and a substrate in a proprietary manufacturing process to produce arrays that can perform many assays simultaneously. (PX0061 (Illumina) at 8; *see* PX0091 (Illumina) at 16.) This facilitates large-scale analysis of genetic variation and biological function in a unique, high-throughput, cost-effective, and flexible manner. (PX0061 (Illumina) at 8; *see* PX0091 (Illumina) at 16.)

Response to Finding No. 24.2

[redacted]

[redacted]

24.3 In 2018, 2019 and 2020, total array revenue comprised 17%, 13% and 11%, respectively, of total revenue. (PX0061 (Illumina) at 8; *see* PX0091 (Illumina) at 16.)

Response to Finding No. 24.3

Complaint Counsel does not disagree with the proposed finding to the extent it refers to Illumina's revenues.

25. Consumables. Illumina has developed various library preparation and sequencing kits to simplify workflows and accelerate analysis. (PX0061 (Illumina) at 8; *see also* deSouza (Illumina) Tr. 2313, 2355–56; Berry (Illumina) Tr. 826–27, 844–85, 928; PX0091 (Illumina) at 15; [redacted]).)

Response to Finding No. 25

[redacted]

25.1 Illumina's sequencing applications include whole-genome sequencing kits, which sequence entire genomes of any size and complexity, and targeted resequencing kits, which can sequence exomes, specific genes, RNA or other genomic regions of interest. (PX0061 (Illumina) at 8; *see also* [redacted]; Berry (Illumina) Tr. 822–24; Aravanis (Illumina) Tr. 1958–59; [redacted]); PX0091 (Illumina) at 21.)

Response to Finding No. 25.1

Complaint Counsel does not disagree with the proposed finding.

25.2 Illumina's sequencing kits maximize the ability of its customers to characterize the target genome accurately and are sold in various configurations, addressing a wide range of applications. (PX0061 (Illumina) at 8; *see also* [redacted]; PX7076 (Berry (Illumina) Dep. at 67–68).)

Response to Finding No. 25.2

Complaint Counsel does not disagree with the proposed finding.

25.3 Customers use Illumina's array-based genotyping consumables for a wide range of analyses, including diverse species, disease-related mutations and genetic characteristics associated with cancer. (PX0061 (Illumina) at 8; *see also* deSouza (Illumina) Tr. 2325–26; PX0091 (Illumina) at 24; PX7076 (Berry (Illumina) Dep. at 158).)

Response to Finding No. 25.3

The proposed finding is vague. It is vague because it does not identify or specify which Illumina "array-based genotyping consumables" are used in the listed analyses. Therefore, this Court should disregard the proposed finding.

25.4 Customers can select from a range of human, animal, and agriculturally relevant genome panels or create their own custom arrays to investigate millions of genetic markers targeting any species. (PX0061 (Illumina) at 8; *see also* PX7076 (Berry (Illumina), Dep. at 163–64).)

Response to Finding No. 25.4

The proposed finding is vague and misleading. It is vague because it refers, in turn, to "a range of human, animal, and agriculturally relevant genome panels," and "any species," without quantifying "range," or specifying "any" respectively. Therefore, this Court should disregard the proposed finding.

26. Services. Illumina provides whole-genome sequencing, genotyping, NIPT, and product support services. (PX0061 (Illumina) at 9; *see also* Berry (Illumina) Tr. 866–68; [redacted] at 24, [redacted].)

Response to Finding No. 26

[redacted]

27. Illumina's CLIA-certified, CAP-accredited laboratory provides human whole-genome sequencing services. (PX0061 (Illumina) at 9; *see also* [redacted] PX7073 (Aravanis (Illumina) IHT at 32).) Using Illumina's services, customers can perform whole-genome sequencing projects and microarray projects (including large-scale genotyping studies and whole-genome association studies). (PX0061 (Illumina) at 9; *see also* PX0091 (Illumina) at 24.)

Response to Finding No. 27

[redacted]

28. Illumina also provides NIPT services through its partner laboratories that direct samples to Illumina on a test send-out basis in Illumina's CLIA-certified, CAP-accredited laboratory. (PX0061 (Illumina) at 9; PX7063 (Berry (Illumina) IHT at 24, 207–08).)

Response to Finding No. 28

The proposed finding is vague because it does not define the terms "test send-out basis," "CLIA-certified," and "CAP-accredited." Therefore, this Court should disregard the proposed finding.

29. In addition, Illumina also offers support services to customers who have purchased its products. (PX0061 (Illumina) at 9; *see also* PX7076 (Berry (Illumina) Dep. at 58–59, 87–88, 108–109); PX7063 (Berry (Illumina) IHT at 14).)

Response to Finding No. 29

The proposed finding is vague because it is not clear what constitutes "support services." Therefore, this Court should disregard the proposed finding.

30. Clinical Applications. Through its Lab Services division, Illumina offers clinical sequencing services, including NIPT testing, direct-to-consumer ("DTC") genomic testing, more recently, COVID testing, and its TruSight series of therapy selection tests, including TSO-500. (*See* PX0091 (Illumina) at 17–24.)

Response to Finding No. 30

The proposed finding is vague because the terms "clinical sequencing" and "direct-to-consumer genomic testing" are not defined. Therefore, this Court should disregard the proposed

finding.

30.1 The first COVID-19 viral sequence was on an Illumina machine and now genomic surveillance has emerged as a critical tool in the global fight against the pandemic, with over 70 countries now using Illumina platforms for COVID-19 variant tracking. (PX0377 (Illumina) at 2; *see also* Aravanis (Illumina) Tr. 1950–51; [redacted]

Response to Finding No. 30.1

[redacted]

4. **Research and Development, Marketing and Distribution**

31. Research and Development. Illumina has historically made substantial investments in research and development. (PX0061 (Illumina) at 9; Aravanis (Illumina) Tr. 1949–50; deSouza (Illumina) Tr. 2354–55.) Illumina's research and development efforts prioritize continuous innovation coupled with product evolution. (PX0061 (Illumina) at 9; deSouza (Illumina) Tr. 2328–30, 2353; Aravanis (Illumina) Tr. 1948.)

Response to Finding No. 31

The proposed finding is vague because the term "substantial" is ambiguous; it is not clear what constitutes a substantial investment. Therefore, this Court should disregard the proposed finding.

31.1 Illumina's research and development expense in 2020, 2019, and 2018 was $682 million, $647 million, and $623 million, respectively. (PX0061 (Illumina) at 9; Aravanis (Illumina) Tr. 1948; deSouza (Illumina) Tr. 2354.)

Response to Finding No. 31.1

Complaint Counsel has no specific response to this proposed finding.

31.2 Illumina expects research and development expense to increase during 2021 to support business growth and continuing expansion in research and product-development efforts. (PX0061 (Illumina) at 9.)

Response to Finding No. 31.2

Complaint Counsel has no specific response to this proposed finding.

31.3 Illumina's research and development efforts have enabled Illumina to dramatically lower the cost of sequencing over time. (deSouza (Illumina) Tr. 2327–31.)

Response to Finding No. 31.3

The proposed finding is vague and unsupported. It relies solely upon the self-serving testimony of Illumina CEO Francis deSouza to assert that Illumina's research and development efforts have enabled it to dramatically lower the cost of sequencing over time. Additionally, the terms "dramatically" and "over time" are ambiguous. It is not clear how much the cost of sequencing has decreased over how many years. Therefore, this Court should disregard the proposed finding.

32. Marketing and Distribution. Illumina markets and distributes its products directly to customers in North America, Europe, Latin America, and the Asia-Pacific region. (PX0061 (Illumina) at 9; *cf.* deSouza (Illumina) Tr. 2373–74; PX7076 (Berry (Illumina) Dep. at 50).) In addition, Illumina sells through life-science distributors in certain markets within Europe, the Asia-Pacific region, Latin America, the Middle East, and Africa. (PX0061 (Illumina) at 9; *see also* PX7107 (deSouza (Illumina) Dep. at 79–80).)

Response to Finding No. 32

The proposed finding is vague because it does not define the term "life-science distributors"; does not specify what markets are included in "certain markets"; and does not identify what products it allegedly distributes. Therefore, this Court should disregard the proposed finding.

5. **Competition**

33. Illumina faces intense competition, which could render is products obsolete, result in significant price reductions, or substantially limit the volume of products that Illumina sells. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2331–32, 2385–86; Aravanis (Illumina) Tr. 1855–58; [redacted]

Response to Finding No. 33

[redacted]

[redacted]

34. Illumina competes with third parties that manufacture and market products and services for analysis of genetic variation and biological function. (PX0061 (Illumina) at 10, 14.) For instance, these competitors offer products and services for sequencing, SNP genotyping, gene expression, and molecular diagnostics markets, including PCR platforms, microarray platforms and proteomics platforms. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2318–20; *cf.* Berry (Illumina) Tr. 813.)

Response to Finding No. 34

The proposed finding is vague, misleading, incomplete, and unreliable, and it should be disregarded. It is vague because it does not define "genetic variation and biological function," "SNP genotyping," "gene expression," or "molecular diagnostics markets." It relies in part on the self-serving testimony of Mr. deSouza and Ms. Berry, Illumina executives who receive additional financial compensation as a result of the Transaction.

It is misleading and incomplete to the extent that it suggests that Illumina faces any meaningful competition to serve MCED test developers or that Illumina is not the dominant provider of NGS instruments and reagents across all markets. Illumina considers itself "the global leader in sequencing- and array-based solutions for genetic and genomic analysis." (PX0061 at 005 (Illumina 2020 Form 10-K)). Several market participants refer to Illumina as the "dominant" supplier in the NGS space. [redacted]

Moreover, Illumina is the only viable NGS sequencing option for MCED tests developers, as evidenced by the fact that [redacted] Further, sufficient and timely entry of a new short-read NGS platform that is suitable for MCED test developers is unlikely. (*see* CCFF ¶¶ 1501-1767). Therefore, it is clear that Illumina does not face "intense competition," and it faces no competition at all to serve MCED test developers.

In addition, MCED market participants, as well as Illumina itself, have testified that non-NGS options, such as PCR platforms and microarray platforms, are not viable substitutes for MCED test developers. (*see* CCFF ¶¶ 1399-1500). Illumina materials state that no other DNA analysis technology can analyze as many DNA fragments as NGS or characterize almost all biomarkers contained within each fragment like NGS. (*See* PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) (". . . qPCR can only detect known sequences. In contrast, NGS is a hypothesis-free approach that does not require prior knowledge of sequence information."); *see also* PX7097 (Felton (Thermo Fisher) Dep. at 39) (testifying that PCR is generally not used to detect unknown variants)). MCED test developers, such as

[redacted]

35. In some cases, Illumina competes for the resources its customers allocate for purchasing a wide range of sequencing and non-sequencing products used to analyze genetic variation and biological function, some of which are complementary or adjacent to Illumina's own; in other cases, Illumina's products face direct competition as customers choose among sequencing and non-sequencing products that are designed to address the same use case or answer the same biological question. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2323–26; [redacted]).)

Response to Finding No. 35

[redacted]

[redacted]

[redacted]

36. Some of Illumina's competitors have, or will have, substantially greater financial, technical, research, and other resources than Illumina does, along with larger, more established marketing, sales, distribution, and service organizations. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2311–12; *cf.* Aravanis (Illumina) Tr. 1857–61.) In addition, they may have greater name recognition than Illumina does in the markets Illumina addresses, and in some cases a larger installed base of systems. (PX0061 (Illumina) at 10.)

Response to Finding No. 36

The proposed finding is vague, misleading, incomplete, unsupported, and unreliable, and it should be disregarded. It is vague because it does not define "other resources," or which markets it is referring to by "the markets Illumina addresses." It relies in part on the self-serving

testimony of Mr. deSouza and Dr. Aravanis, Illumina executives who receive additional financial compensation as a result of the Transaction. It is also unsupported because it merely copies a line from Illumina's 2021 Form 10-K, and the cited trial testimony does not contain anything relevant to these arguments.

It is misleading and incomplete to the extent that it suggests that Illumina faces any meaningful competition to serve MCED test developers or that Illumina is not the dominant provider of NGS instruments and reagents across all markets. Illumina considers itself "the global leader in sequencing- and array-based solutions for genetic and genomic analysis." (PX0061 at 005 (Illumina 2020 Form 10-K)). Several market participants refer to Illumina as the "dominant" supplier in the NGS space. [redacted]

Moreover, Illumina is the only viable NGS sequencing option for MCED tests developers, as evidenced by the fact that [redacted] Further, sufficient and timely entry of a new short-read NGS platform that is suitable for MCED test developers is unlikely. (*See* CCFF ¶¶ 1501-1767). Therefore, it is clear that Illumina does not face "intense competition," and it faces no competition at all to serve MCED test developers. It is also well known in the MCED testing space that, as Dr. Chahine of Helio testified, the Illumina platform is "by far [ ] the preferred one that's used even at third-party shops" and the "leading one for many different [ ] reasons."

(Chahine (Helio) Tr. 1044).

In addition, MCED market participants, as well as Illumina itself, have testified that non-NGS options, such as PCR platforms and microarray platforms, are not viable substitutes for MCED test developers. (*See* CCFF ¶¶ 1399-1500). Illumina materials state that no other DNA analysis technology can analyze as many DNA fragments as NGS or characterize almost all biomarkers contained within each fragment like NGS. (*See* PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) (". . . qPCR can only detect known sequences. In contrast, NGS is a hypothesis-free approach that does not require prior knowledge of sequence information."); *see also* PX7097 (Felton (Thermo Fisher) Dep. at 39) (testifying that PCR is generally not used to detect unknown variants)). MCED test developers, such as

[redacted]

37. Illumina expects new competitors to emerge and the intensity of competition to increase as existing companies develop new or improved products and as new companies enter the market with new technologies. (Aravanis (Illumina) Tr. 1860–61, 1866; Berry (Illumina) Tr. 813; PX7079 (Flatley (Illumina) Dep. at 57–58); PX2017 (Illumina) at 40, 43; [redacted]; PX0061 (Illumina) at 10, 15.) One or more of Illumina's competitors may render one or more of Illumina's technologies obsolete or uneconomical. (PX0061 (Illumina) at 15; *see also* Aravanis (Illumina) Tr. 1854–58.)

Response to Finding No. 37

[redacted]

[redacted]

38. In the NGS space in particular, Illumina expects there will be intensifying competition in the near future both from incumbent players and new entrants. (deSouza (Illumina) Tr. 2318–20.)

Response to Finding No. 38

The proposed finding is vague, misleading, incomplete, and unreliable, and it should be

disregarded. It is vague because it does not define "intensifying competition." It relies in part on the self-serving testimony of Ms. Berry and Dr. Aravanis, Illumina executives who receive additional financial compensation as a result of the Transaction.

It is misleading and incomplete to the extent that it suggests that Illumina faces any meaningful competition to serve MCED test developers or that Illumina is not the dominant provider of NGS instruments and reagents across all markets. Illumina considers itself "the global leader in sequencing- and array-based solutions for genetic and genomic analysis." (PX0061 at 005 (Illumina 2020 Form 10-K)). Several market participants refer to Illumina as the "dominant" supplier in the NGS space. [redacted]

Moreover, Illumina is the only viable NGS sequencing option for MCED tests developers, as evidenced by the fact that [redacted] Further, sufficient and timely entry of a new short-read NGS platform that is suitable for MCED test developers is unlikely. (*See* CCFF ¶¶ 1501-1767). Therefore, it is clear that Illumina does not face "intense competition," and it faces no competition at all to serve MCED test developers. It is also well known in the MCED testing space that, as Dr. Chahine of Helio testified, the Illumina platform is "by far [ ] the preferred one that's used even at third-party shops" and the "leading one for many different [ ] reasons." (Chahine (Helio) Tr. 1044). Therefore, this Court should disregard the proposed finding.

B. GRAIL

1. Overview

39. GRAIL is a healthcare company focused on saving lives and improving health by pioneering new technologies for early cancer detection. (PX0043 (GRAIL) at 4.) Using its platform technology, GRAIL has developed a multi-cancer early detection blood test that has demonstrated in clinical studies the ability to detect more than 50 types of cancer, across all stages, and localize the cancer signal with a high degree of accuracy, from a single blood draw. (PX0043 (GRAIL) at 4.)

Response to Finding No. 39

The proposed finding is outright false, unsupported, incomplete, misleading, and vague. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394 (Appendix B: Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See, e.g.*, RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect

those cancers early. (*See, e.g.*, CCFF ¶ 6223). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman,

acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

The proposed finding is incomplete and misleading to the extent it suggests that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population. The CSO accuracy numbers reported in CCGA do not indicate the likelihood that a particular CSO prediction accurately identifies the location of an individual's' cancer because (1) CCGA did not involve an asymptomatic screening population, (2) the study excluded false positives when assessing CSO accuracy, and (3) Grail counts Galleri's CSO predictions as "correct" even in instances when Galleri does not actually identify the location of the underlying cancer. (*See* Complaint Counsel's Post-Trial Reply Brief at 50-54). Additionally, Galleri's CSO prediction feature does not obviate the need for additional diagnostic evaluation, including diagnostic imaging such as PET-CT. (*See* PX0063 at 002 (Grail, https://grail.com/galleri, accessed Apr. 29, 2021) ("A test result of 'Cancer Signal Detected' requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer").

The CCGA study did not involve a real-world population, but rather was a case-control

study that involved individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Among other factors, some of the blood samples in CCGA were "collected from participants with cancer after biopsies had been carried out," which the authors note "could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." Galleri's reported tissue of origin accuracy was worse for Stage I-II cancers than for Stage III-IV cancers in CCGA (*See* RX3430 at 6, Figure 4 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2]). This fact suggests that Galleri's CSO performance will be worse in an asymptomatic screening population that does not include previously diagnosed Stage III and Stage IV cancer patients, as the CCGA study did.

The proposed finding is also vague because the phrase "high degree of accuracy" is undefined and unexplained. Therefore, this Court should disregard the proposed finding.

2. **Formation**

40. In February 2013, Illumina acquired Verinata, a company that had developed a noninvasive prenatal test ("NIPT") for fetal chromosomal abnormalities using a blood sample. (RX3337 (Illumina) at 1.) In the first 100,000 women that received the non-invasive prenatal test from Verinata, some unusual signs were identified: in a handful of cases, a signal was detected in the mother's blood that was initially believed to be a false signal indicating a genetic abnormality in the fetus. (Aravanis (Illumina) Tr. 1868–69; *see generally* RX2547 (Bianchi et al., 2015).)

Response to Finding No. 40

The proposed finding is vague and misleading and should be disregarded. It is vague because it lacks context and does not define the term "unusual signs." It is also misleading to the extent that it suggests that Illumina's acquisition of Verinata was the source of discovery leading to Galleri. This erroneous claim is flatly contradicted by record evidence. First, multiple other individuals were already exploring the potential use of cfDNA for an MCED test well before Illumina's acquisition of Verinata in 2013. For example, Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that could provide early detection of colon cancer. (CCFF ¶ 357). In March 2009, Dr. Ahlquist told Exact's CEO, Kevin Conroy, of his vision for detecting many or most cancers from a simple blood draw. (CCFF ¶ 358). Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (CCFF ¶ 358). Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier, (CCFF ¶ 359), [redacted] At the same time Exact was working with Dr. Ahlquist on its MCED test, Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (CCFF ¶ 361). Dr. Vogelstein was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies," (CCFF ¶ 363), and he ran

clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (CCFF ¶ 365). Ultimately, Dr. Vogelstein became a co-founder of Thrive, (CCFF ¶ 366), and his discoveries led to the creation of Thrive's CancerSEEK MCED test. (CCFF ¶ 364).

Second, Illumina's internal documents directly contradict its claims that the Verinata transaction was the source of the discovery leading to Galleri. Specifically, Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings of National Academy of Science journal in 2008 presenting research on the detection of fetus chromosome trisomy using cfDNA. (CCFF ¶ 354). Dr. Gao used the research from his 2008 paper with Dr. Dennis Lo to begin research on the use of cfDNA for cancer screening. (CCFF ¶ 354). As early as 2009, Dr. Gao published a paper on DNA methylation for use in applications such as cancer detection in 2009 with Singlera co-founder Professor Kun Zhang of the University of California San Diego. (CCFF ¶ 355). By 2012, Dr. Lo's research caught the attention of Illumina. In August 2012, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina's SVP of Corporate and Venture Development, Nicholas Naclerio, to alert Naclerio of research by Dr. Dennis Lo. (CCFF ¶ 369). Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [noninvasive prenatal testing]," (CCFF ¶ 371), and suggested that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (CCFF ¶ 372). Just one month later, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought to review Dr. Lo's "filed patent applications." (CCFF ¶ 373). In notes from the call, Illumina's attendees wrote the question, "How will a clinician use

this type of data?" (CCFF ¶ 373). Responses to the question included "*Blood biopsy – non-invasive screening" and "Potential for detecting cancer prior to actual detection of a primary tumor*." (CCFF ¶ 363 (emphasis added)). Therefore, this Court should disregard the proposed finding.

41. Meredith Halks-Miller, the laboratory director at Illumina, approached Illumina's leadership about these unusual signals. (PX7048 (Klausner (GRAIL) IHT at 49–50.) Illumina formed a team and a program to evaluate these signals to follow up with patients and prescribing physicians and discovered that these women had undiagnosed cancer. (Aravanis (Illumina) Tr. 1868–69, 1873–74; PX7079 (Flatley (Illumina) Dep. at 35–37; PX7048 (Klausner (GRAIL) IHT at 49–50.) This discovery led to the realization that early cancer could be detected in the blood. (Aravanis (Illumina) Tr. 1868–69, 1873–74; PX7079 (Flatley (Illumina) Dep. at 35–37; PX7048 (Klausner (GRAIL) IHT at 49–50.)

Response to Finding No. 41

[redacted]

42. At the same time, Illumina was developing a liquid biopsy technology to look at cancer signals in late-stage cancer for the purposes of therapy selection for advanced cancer patients. (Aravanis (Illumina) Tr. 1869.) There was data from that project which applied to some early-stage cancer samples that also suggested early-stage cancer detection might be possible. (Aravanis (Illumina) Tr. 1869.)

Response to Finding No. 42

Complaint Counsel has no specific response to the proposed finding.

43. Because of the aforementioned discoveries, Illumina decided to pursue the early detection of cancer in the blood. (Aravanis (Illumina) Tr. 1868–69; PX7079 (Flatley (Illumina) Dep. at 35–37; PX7048 (Klausner (GRAIL) IHT) at 49–50.)

Response to Finding No. 43

Complaint Counsel has no specific response to the proposed finding.

44. In 2015, Illumina formed GRAIL with the goal of achieving the "holy GRAIL" in the war on cancer: a test—enabled by Illumina's sequencing technology—to detect multiple types of cancer in asymptomatic individuals through a blood draw. (Aravanis (Illumina) Tr. 1872; PX0036 (GRAIL) at 5; PX7079 (Flatley (Illumina) Dep. at 35–37); PX7104 (Aravanis (Illumina) Dep. at 159–160).)

Response to Finding No. 44

The proposed finding is unsupported to the extent that none of the cited materials establish when Grail was formed. Notwithstanding the foregoing, Complaint Counsel does not disagree that Grail was formed in 2015-2016. (*See* CCFF ¶¶ 24-39). Complaint Counsel has no specific response to the remainder of the proposed finding.

45. It was a "moonshot" ambition—as Illumina's then-CEO, Jay Flatley (Illumina), put it at the time, "GRAIL is going after a much more daunting technology, scientific and biological problem that [no other companies] to [Illumina's] knowledge . . . have even begun to address". (RX3970 (Illumina) at 10.)

Response to Finding No. 45

The proposed finding is misleading to the extent it relies only on a single statement by Illumina's then-CEO to suggest that no other companies were pursuing multi-cancer early detection tests at the time Grail was created. As the weight of the evidence shows, there were multiple companies pursuing MCED tests at or before this time. The proposed finding is also confusing to the extent the term "moonshot" and the phrase "moonshot ambition" do not appear in the cited material and are undefined. Therefore, this Court should disregard the proposed

finding.

46. By forming GRAIL, Illumina hoped to "[a]ccelerat[e] development of the ctDNA cancer screening market by 10 years". (RX1914 (Illumina) at 7.) Thus, from the start, Illumina viewed GRAIL as an extension of its core goal of expanding and accelerating adoption of NGS technology in new applications, paving the way for NGS-based screening tests and spurring innovation. (Aravanis (Illumina) Tr. 1870–71, 1905–1907; *cf.* [redacted]

Response to Finding No. 46

[redacted]

47. To position GRAIL for its moonshot objective, Illumina seeded GRAIL with the talent, R&D capabilities, development plans and data it would need to investigate how to use NGS technology for multi-cancer early detection through foundational, population-scale trials. (PX7107 (deSouza (Illumina) Dep. at 182–83).)

Response to Finding No. 47

The proposed finding is unsupported to the extent the cited deposition excerpt does not establish that Illumina provided Grail with any "development plans and data." Nor does the cited provision establish that Illumina provided Grail with sufficient resources to develop a multicancer early detection test "through foundational, population-scale trials." Therefore, this Court should disregard the proposed finding.

48. However, GRAIL would also require a substantial amount of capital to conduct the foundational clinical trials necessary to build the data sets for its machine learning algorithm. (PX7079 (Flatley (Illumina) Dep. at 92–94); PX7065 (Aravanis (Illumina) Dep. at 62–64).)

Response to Finding No. 48

Complaint Counsel has no specific response to the proposed finding.

49. Given the high risks of failure at this early stage, Illumina decided to bring in outside investors to spread the risk while ensuring GRAIL had the capital it needed to move from concept through clinical trials, and the freedom of a biotech startup to experiment and fail in pursuit of its "moonshot" objective. (Aravanis (Illumina) Tr. 1772–73; PX7079 (Flatley (Illumina) Dep. at 92–94).)

Response to Finding No. 49

Complaint Counsel has no specific response to the proposed finding.

49.1 To that end, in February 2017, Illumina completed a capital raise in connection with which Illumina reduced its stake in GRAIL to less than 20%. (RX3972 (Illumina) at 2; RX3984 (Illumina) at 14; *see* deSouza (Illumina) Tr. 2202.)

Response to Finding No. 49.1

Complaint Counsel has no specific response to the proposed finding.

50. Although Illumina reduced its investment in GRAIL in 2017, Illumina remained heavily invested in GRAIL's success. In addition to its equity stake in GRAIL (around 12% of GRAIL's outstanding shares on a fully diluted basis before the transaction closed), Illumina has a long-term agreement to supply GRAIL with NGS instruments and reagents for its genomic testing needs, and also had the right to receive approximately [redacted] of future net sales of any GRAIL oncology products or services. [redacted]; *see also* Aravanis (Illumina) Tr. 1876–77; RX3984 (Illumina) at 14–15.)

Response to Finding No. 50

[redacted]

3. **GRAIL Today**

51. By late 2020, GRAIL had built a multi-disciplinary organization of scientists, engineers, and physicians to use the power of next-generation sequencing (NGS), population-scale clinical studies, and state-of-the-art computer science and data science to overcome one of medicine's greatest challenges: detecting cancer early, when it can be cured. (PX0043 (GRAIL) at 4; *see also* Aravanis (Illumina) Tr. 1907; deSouza (Illumina) Tr. 2334–35.)

Response to Finding No. 51

The proposed finding is vague and misleading to the extent that it suggests cancer can only be cured when detected early or that cancer is always cured when detected early. Additionally, the term "state-of-the-art" is vague and ambiguous when used to describe computer science and data science.

The proposed finding is vague in stating GRAIL has built something "to overcome" one of "medicine's greatest challenges" because it is not clear what overcome means in this context. It is misleading to the extent it suggests that GRAIL has actually overcome any such challenge, because there is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or for that matter, eight. As of today, Galleri has been clinically shown to detect only seven types of early-stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394).

[redacted]

- [redacted]

[redacted]

52. Using GRAIL's platform technology, GRAIL developed a multi-cancer early detection blood test that has demonstrated in clinical studies the ability to detect more than 50 types of cancer, across all stages, and localize the cancer signal with a high degree of accuracy, from a single blood draw. (PX0043 (GRAIL) at 4; *see also* Aravanis (Illumina) Tr. 1892, 1897; deSouza (Illumina) Tr. 2335; PX7104 (Aravanis (Illumina) Dep. at 238).)

Response to Finding No. 52

The proposed finding is incomplete, misleading, and vague. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic

population, or ten, or for that matter, eight. As of today, Galleri has been clinically shown to detect only seven types of early-stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394).

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer *early* detection test (2) for use in screening an asymptomatic population. (*See, e.g.,* RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.,* CCFF ¶ 6233). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population. CCGA did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). The authors of the CCGA-3 substudy – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation

of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of Grail's CCGA-2 study also provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298).

The proposed finding is also misleading to the extent it suggests that Galleri's algorithmic cancer signal of origin prediction is capable of definitively localizing cancer "with a high degree of accuracy, from a single blood draw." Reliable clinical data does not exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population. The Galleri CSO accuracy numbers reported in CCGA-3 do not indicate the likelihood that a particular CSO prediction accurately identifies the location of an individual's' cancer because (1) CCGA did not involve an asymptomatic screening population, (2) the study excluded false positives when assessing CSO accuracy, and (3) Grail counts Galleri's CSO predictions as "correct" *even in instances when Galleri does not actually identify the location of the underlying cancer*. (*See* Complaint Counsel's Post-Trial Reply Brief at 50-54).

The proposed finding is also incomplete and misleading to the extent it suggests that no further diagnostic work (beyond a "single blood draw") would be necessary to determine the accuracy of a positive cancer signal reported by Galleri. [redacted] When assessed in a screening setting involving asymptomatic normal-risk participants, over half of positive Galleri results were falsely positive, meaning the test "detected" a signal for cancer among participants who did not have cancer. (*See* CCFF ¶ 6292.)

A positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). When asked whether Galleri could "identify the cancer signal of origin just through the blood," Grail's CEO, Hans Bishop clarified that "the appropriate workup associated with that cancer signal of origin" would be required for confirmation, including the use of ultrasound and biopsy. (Bishop (Grail) Tr. 1387). Mr. Bishop testified at trial that some patients may need to undergo a body scan to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). [redacted]

Interim results from PATHFINDER, an actual interventional trial for Galleri, indicate that additional imaging testing was required for positive results 90 percent of the time. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) ("Most participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)."). Over half the positive results in PATHFINDER with diagnostic resolution were determined to be false positives (55.4%) and 25 percent of participants who received falsely positive results underwent at least one invasive procedure. (RX3041 at 004 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). [redacted]

53. GRAIL undertook a rigorous, comprehensive, multi-omic discovery approach to explore and identify the most promising biological hallmarks of cancer. (PX0043 (GRAIL) at 4, 96; *see also* Aravanis (Illumina) Tr. 1880–81, 1916–18.)

Response to Finding No. 53

The proposed finding is vague because the terms "multi-omic" and "biological hallmarks" are not defined and the terms "rigorous," "comprehensive," and "most promising" are ambiguous. Therefore, this Court should disregard the proposed finding.

53.1 GRAIL invested significant capital and resources in its foundational studies, which have collectively enrolled approximately 115,000 participants, to build what GRAIL believes are the largest linked datasets of genomic and clinical data in the

cancer field. (PX0043 (GRAIL) at 4, 96; *see also* PX7083 (Bishop (GRAIL) Dep. at 63); PX7069 (Bishop (GRAIL) IHT at 191–92).)

Response to Finding No. 53.1

The proposed finding is vague, unsupported, and speculative. It relies solely upon Grail documents and the self-serving testimony of former Grail Hans Bishop to support Grail's speculative "belief" that it has the largest linked datasets of genomic and clinical data in the cancer field. No outside sources, academic articles, or scientific studies are cited to support this purported belief. Additionally, the term "significant" is ambiguous; it is not clear what constitutes significant capital and resources. Therefore, this Court should disregard the proposed finding.

54. In order to determine the optimal means of cancer detection, GRAIL compared the performance of three different NGS approaches—mutations, chromosomal alterations and methylation patterns—in head-to-head studies. (PX0043 (GRAIL) at 96; *see also* Aravanis (Illumina) Tr. 1880–81; [redacted]

Response to Finding No. 54

[redacted]

55. While all three markers were capable of detecting cancer, GRAIL found that methylation profiling yielded significantly better results for cancer detection than was observed by interrogating mutations or chromosomal alterations, alone or in combination. (PX0043 (GRAIL) at 96; *see also* Aravanis (Illumina) Tr. 1881; Ofman (GRAIL) Tr. 3291–92.)

Response to Finding No. 55

The proposed finding is unsupported, vague, and ambiguous. It does not cite any outside sources, academic articles, or scientific studies to support the results of Grail's purported comparison of mutations, chromosomal alterations, and methylation patterns. Furthermore, it does not define the term "chromosomal alternations" and does not quantify what "significantly better results" means. Therefore, this Court should disregard the proposed finding.

56. After comprehensive analysis of whole-genome methylation patterns, GRAIL discovered highly informative and low-noise methylation regions for cancer signal detection and localization, leading it to develop a targeted methylation approach with superior performance and lower costs than whole-genome methylation. (PX0043 (GRAIL) at 96; *see also* Aravanis (Illumina) Tr. 1891; Bishop (GRAIL) Tr. 1373; PX7104 (Aravanis (Illumina) Dep. at 182–83, 188); PX7072 [redacted] at 55, [redacted]

Response to Finding No. 56

[redacted]

57. This approach helps solve a core problem in detecting cancer early in asymptomatic individuals: the low level of cancer signal circulating in the blood. (PX0043 (GRAIL) at 96; [redacted] *see also* PX0036 (GRAIL) at 7.)

Response to Finding No. 57

[redacted]

[redacted]

58. While methylation profiling is the approach GRAIL is using with Galleri, it continues to evaluate multi-omic approaches including evaluation of additional analytes and biofluids. (PX0043 (GRAIL) at 96; [redacted] Ofman (GRAIL) Tr. 3301, 3303–04; [redacted]

Response to Finding No. 58

[redacted]

4. **GRAIL's Galleri Test**

59. GRAIL's multi-cancer early detection test, Galleri, is designed as a screening test for asymptomatic individuals over 50 years of age. (PX0043 (GRAIL) at 96; PX7083 (Bishop (GRAIL) Dep. at 25); PX7069 (Bishop (GRAIL) IHT at 149).) GRAIL commercially launched Galleri in May 2021 as a laboratory developed test (LDT.) (Aravanis (Illumina) Tr. 1892; Freidin Tr. 2968–69.)

Response to Finding No. 59

The proposed finding is incorrect because Grail commercially launched Galleri in June 2021. (Aravanis (Illumina) Tr. 1892; Freidin Tr. 2968–69).

60. Galleri has the potential to transform cancer care and population health. (PX0043 (GRAIL) at 5, 97; *see also* Ofman (GRAIL) Tr. 3279–80; PX7092 (Ofman (GRAIL) Dep. at 22.)

Response to Finding No. 60

The proposed finding is vague, unsupported, and misleading. The proposed finding is vague because the term "transform" is ambiguous and undefined. The proposed finding is unsupported because it relies solely on Grail's self-serving statements, uncorroborated by any neutral or third-party testimony or evidence. The proposed finding is misleading because the

primary underlying source cited, Grail's own S-1 statement, does not state that Grail "has" the potential stated, merely that Grail "*believes*" Grail has the potential stated. (*See* PX0043 (Grail) at 005, 097 (Grail 2020 Form S-1) ("*We believe* our first anticipated commercially available product, Galleri, has the potential to transform cancer care and population health.") (emphasis added)). Complaint Counsel does not disagree that MCED testing broadly is poised to revolutionize how cancer is detected and treated. However, this Court should disregard the proposed finding for the reasons stated above.

61. GRAIL has demonstrated that the Galleri test can identify over 50 types of cancers, over 45 of which lack recommended screenings. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312; Section I.A *infra*).)

Response to Finding No. 61

The proposed finding is incomplete and misleading. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic screening population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of today, Galleri has been clinically shown to detect only seven types of early-stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394 (Appendix B: Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

Respondents seek to conflate the identification of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer early detection test (2) for use in

screening an asymptomatic population. (*See, e.g.*, RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The proposed finding itself uses the term "screening procedure," confirming that the relevant metric is Galleri's ability to screen for cancers in asymptomatic patients. The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.*, CCFF ¶ 6233). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies"

beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). [redacted] In their own proposed findings of fact, Respondents admit that "for an early cancer screening test, whose target population comprises asymptomatic individuals who do not have a diagnosis of cancer, the clinical study cannot use samples from cancer patients" if it is to represent "valid scientific evidence used to determine the effectiveness of a device." (*See* RPFF ¶¶ 319-320).

The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Thomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

Finally, Complaint Counsel notes that the proposed finding is unreliable because

Respondents cite a Grail financial filing and the self-serving testimony of a Grail executive for the proposed finding, rather than providing specific references to the clinical studies themselves. For the above reasons, the proposed finding should be disregarded.

62. Data shows that when Galleri detects cancer, it is also able to localize the cancer signal with high accuracy. (*See* Bishop (GRAIL) Tr. 1387, [redacted]

Response to Finding No. 62

[redacted]

62.1 In the second sub-study (CCGA-2) of GRAIL's foundational Circulating Cell-Free Genome Atlas Study (CCGA), when a cancer signal was detected, an earlier version of Galleri localized the cancer signal in 96% of the samples, and of these, Galleri correctly localized the cancer signal in 93%. (PX0043 (GRAIL) at 5, 97;

Response to Finding No. 62.1

[redacted]

[redacted]

[redacted]

62.2 Early data also suggested that indolent cancers are unlikely to be detected by Galleri, potentially reducing the problem of treating over-diagnosed cancers. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3289–3290.)

Response to Finding No. 62.2

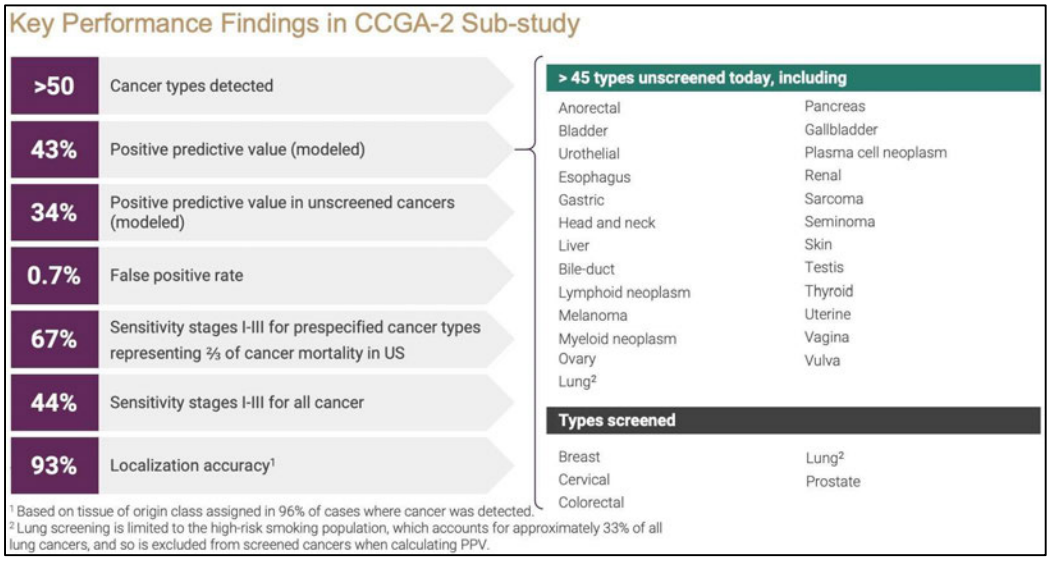
The proposed finding is vague and unreliable. The proposed finding is vague because the term "indolent" is not defined. The proposed finding is also vague because the phrase "early data" and "suggested" are undefined; it is unclear to what data Respondents are referring. Additionally, the proposed finding is unreliable because it fails to cite any underlying data, but instead relies solely on an (uncited) statement in a Grail SEC filing and the self-serving testimony of a Grail executive.

Grail's CCGA study included two types of participants in its cancer arm. Over 70 percent of participants in the cancer arm were identified by "clinical presentation." (*See* CCFF ¶¶ 6244-45). The reminder were diagnosed via other screening tests. Galleri's sensitivity was over three times higher in CCGA-3 for cancer participants diagnosed through "clinical presentation" than for cancer participants diagnosed via other screening tests. (*See* RX3409 at 005 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021) (stating that "overall sensitivity in cancers identified by clinical presentation [63.9% (61.8% - 66.0%)] was higher than that in cancers identified by screening tests [18.0% (15.5% - 20.8%)]")).

It is possible that by "indolent cancers," Respondents mean asymptomatic cancers that have not been previously identified by clinical presentation. Galleri did indeed perform far

worse in the CCGA study at detecting cancers for which there had not yet been "clinical presentation." If that is what Respondents mean, it is a shortcoming, not a strength. The entire point of an MCED test is to identify cancer early in asymptomatic individuals before they would otherwise learn of their cancer through clinical manifestation and diagnosis. The fact that Galleri performed far worse at detecting cancer in this cohort of CCGA does not mitigate a problem; it is itself a problem. For the above reasons, this Court should disregard the proposed finding.

62.3 Below is a summary of the results from the CCGA study (GRAIL S-1 Registration Statement) at 97, 5):



Response to Finding No. 62.3

The proposed finding is confusing. Complaint Counsel is unsure what "fact" Respondents are purporting to offer, beyond the fact that a particular chart appeared in Grail's S-1 statement. To the extent that is the only fact Respondents purport to establish, Complaint Counsel does not disagree that the chart above did in fact appear in Grail's S-1 statement.

To the extent Respondents are attempting to offer the multitude of different statements and findings within that chart for their truth, the proposed finding is improper, unreliable, incomplete, and misleading. The proposed finding would be improper because Respondents

have simply pasted in a chart from a Grail S-1 filing that lists a variety of information. This would represent a compound finding rather than a single finding of fact. Moreover, the chart is not the source of the underlying information and fails to provide reference to the specific source of the information. For example, none of the statistics cite to page numbers from a published academic article. Respondents fail to even provide a PX number for the S-1 filing, in violation of the Court's Post-Trial Order (*See* Post-Trial Order at 3).

The proposed finding is also misleading because it purports to provide a summary of the results of the "CCGA study." The chart itself refers only to the "CCGA-2 Sub-study." The CCGA study involved three separate substudies. (*See* CCFF ¶ 6228). [redacted] Respondents' claim that the chart reflects the "results" from the aggregate CCGA study is thus incorrect.

The proposed finding is also misleading to the extent that it suggests that Galleri can provide early detection of 50+ cancers in an asymptomatic population. As of trial, Galleri had been clinically shown to detect only seven types of early-stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394 (Appendix B: Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See, e.g.*, RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect

signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-2 substudy make this point explicitly: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Respondents state elsewhere in their proposed findings that "for an early cancer screening test, whose target population comprises asymptomatic individuals who do not have a diagnosis of cancer, the clinical study cannot use samples from cancer patients" if it is to represent "valid scientific evidence used to determine the effectiveness of a device." (*See* RPFF ¶¶ 319-320).

Grail also cannot say today how accurate Galleri's predictions will be at localizing cancer in the intended use population. The cancer signal localization numbers reported in CCGA-2 do not indicate the likelihood that a particular Galleri prediction accurately identifies the location of an individual's' cancer because CCGA did not involve an asymptomatic screening population and the study excluded false positives when assessing cancer signal prediction accuracy.

The proposed finding is factually incorrect because the percentages cited do not represent percentages across all instances "when a cancer signal was detected" in the CCGA-2 substudy as Respondents claim. Rather the reported percentages are only for "<u>those with cancer</u> predicted as

having cancer" (*See* RX3430 (Grail) at 009 (M.C. Liu at al., *Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA*, Annals of Oncology (2020) (emphasis added). In other words, the reported percentages exclude false positives – instances in which Galleri returns a positive result to someone who does not have cancer. [redacted] Respondents' use of "imprecise" terminology in the proposed finding is inaccurate, as it erases the false positive issue intrinsic to Galleri's algorithmic cancer prediction feature.

[redacted] Galleri's false positive issue was brought into focus in Grail's PATHFINDER study, which involved asymptomatic patients. Over half the positive results in PATHFINDER with diagnostic resolution were determined to be false positives (55.4%) and 25 percent of participants who received falsely positive results underwent at least one invasive procedure. (RX3041 at 004 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). [redacted]

[redacted] For the above reasons, the only "fact" supported by the proposed finding is that the pasted chart appeared in Grail's S-1 statement; beyond that, this Court should disregard the proposed finding

> 62.4 In those over age 50, Galleri demonstrated a 66% detection rate of Stage II cancers for which there are no current recommended screenings. (PX0043 (GRAIL) at 98.)

Response to Finding No. 62.4

The proposed finding is unreliable and misleading. The proposed finding is unreliable because it purports to offer a fact, while failing to provide any reliable citation to the actual source of that fact. Respondents offer only a cite to a Grail SEC filing; the SEC filing itself provides no attribution for the proposed fact and cites no scientific study or studies. To the extent that Respondents are referring to the CCGA-2 substudy, the authors of that study reported Galleri's Stage II sensitivity to be 43%. (RX3430 at 009 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). (Even that number is not representative of Galleri's performance in an asymptomatic screening population, as explained in Complaint Counsel's Response to RPFF ¶ 62.3, above.)

Complaint Counsel has no idea where the 66% calculation came from. PX0043 provides no details. Grail's CCGA study did include two types of participants in its cancer arm. Over 70 percent of participants in the cancer arm were identified by "clinical presentation." (*See* CCFF ¶¶ 6244-45). The reminder were diagnosed via other screening tests. Galleri's sensitivity was over three times higher in CCGA-3 for cancer participants diagnosed through "clinical presentation" than for cancer participants diagnosed via other screening tests. (*See* RX3409 at 005 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early*

Detection Test Using an Independent Validation Set, Annals of Oncology (2021) (stating that "overall sensitivity in cancers identified by clinical presentation [63.9% (61.8% - 66.0%)] was higher than that in cancers identified by screening tests [18.0% (15.5% - 20.8%)]")).

The entire point of an MCED test is to identify cancer early in asymptomatic individuals. Galleri, however, performed much worse at identifying cancer in CCGA among precisely these individuals – namely, those who learned of their cancer via screening tests rather than through "clinical presentation." It appears as if the phrase "for which there are no current recommended screenings" is intended to drop this inconvenient cohort from Grail's sensitivity calculation. Complaint Counsel cannot be sure – because, again, no reliable citation is provided to the true source of the statistic referenced – but notes that any citation to statistics from the CCGA study that omits the screening portion of the cancer arm is likely to overstate Galleri's performance even more than would otherwise be the case. [redacted] For the above reasons, this Court should disregard the proposed finding.

> 62.5 Galleri could be integrated directly into the existing healthcare pathways delivered to 40 million patients a year who are already going to a physician for their standard-of-care cancer screening. (PX0043 (GRAIL) at 98.)

Response to Finding No. 62.5

The proposed finding is vague because the terms "existing healthcare pathways" and "standard-of-care cancer screening" are ambiguous and not defined. Additionally, the proposed finding is unsupported because it relies solely on a Grail SEC filing to speculate on whether physicians could integrate Galleri into their existing cancer screening methods. Therefore, this

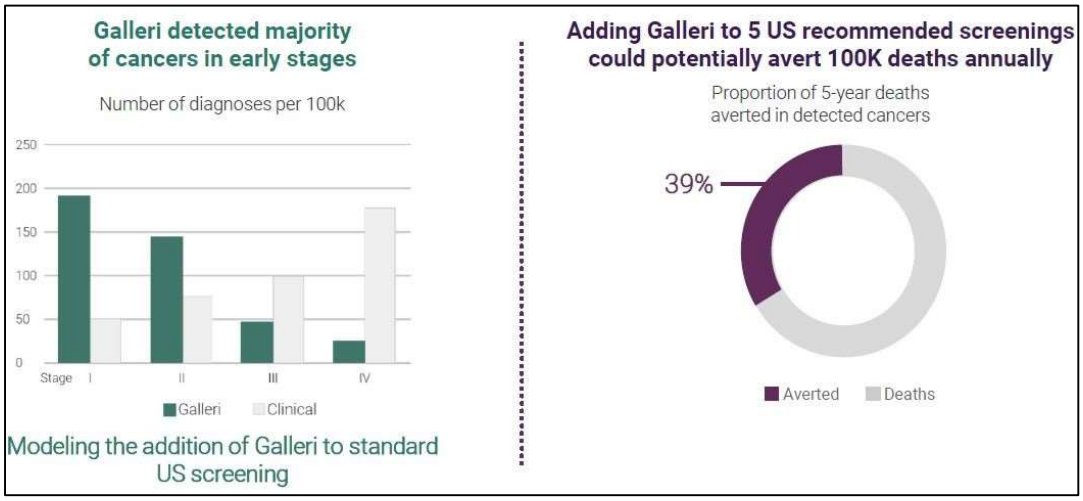
Court should disregard the proposed finding.

63. GRAIL has developed a cancer epidemiology forecast model to estimate the potential impact of multi-cancer early detection testing on cancer stage shift and mortality reduction. (PX0043 (GRAIL) at 6, 98.)

Response to Finding No. 63

The proposed fining is vague because the phrases "cancer epidemiology forecast model" and "stage shift" are undefined.

64. Based on the performance of Galleri in the CCGA-2 study and using 2006 to 2015 SEER data for ages 50–79, GRAIL estimates that by adding Galleri to diagnosis by usual care, there is potential to detect nearly 70% of cancers resulting in death within five years at an earlier stage (excluding cancers that grow too quickly to be detected by any screening program), which would translate to averting potentially 100,000 deaths annually, or 39% of the five-year deaths expected if not for early detection by Galleri. (PX0043 (GRAIL) at 6, 98; [redacted]



Response to Finding No. 64

[redacted]

[redacted]

65. Galleri has the potential to dramatically increase population early cancer detection, reducing the attendant morbidity, mortality and costs of late-stage cancer diagnoses. (PX0043 (GRAIL) at 6, 98; *see also* Ofman (GRAIL) Tr. 3280–81; PX7069 (Bishop (GRAIL) IHT at 24, 204.)

Response to Finding No. 65

The proposed finding is unsupported because it relies solely on Grail's self-serving statements, uncorroborated by any neutral or third-party testimony or evidence. The proposed finding is misleading because the primary underlying source cited, Grail's own S-1 statement, does not state that Grail "has" the potential stated, merely that Grail "*believes*" Grail has the

potential stated. (*See* PX0043 (Grail) at 006, 098 (Grail 2020 Form S-1) ("*We believe* Galleri has the potential to dramatically increase population early cancer detection, reducing the attendant morbidity, mortality and costs of late-stage cancer diagnosis.") (emphasis added)). Complaint Counsel does not disagree that MCED testing broadly is poised to revolutionize how cancer is detected and treated.

66. It has been estimated that a 1% reduction in cancer mortality in the United States would be worth $695 billion in today's dollars from increased quality of life, productivity and survival. (PX0043 (GRAIL) at 6, 98.)

Response to Finding No. 66

Complaint Counsel has no specific response to the proposed finding.

66.1 This estimate does not include intangible benefits such as the decreased emotional burden to family, friends and caregivers. (PX0043 (GRAIL) at 6, 98.)

Response to Finding No. 66.1

Complaint Counsel has no specific response to the proposed finding.

5. **Barriers to Commercial Success**

67. While GRAIL has enormous promise, it must overcome several barriers to achieve success as it shifts its focus from research and development to commercialization. (PX0043 (GRAIL) at 20–69; Bishop (GRAIL) Tr. 1413–14; PX7069 (Bishop (GRAIL) Dep. at 186).)

Response to Finding No. 67

The proposed finding is vague because it refers to a general list of business barriers, which are broadly faced by many companies, instead of identifying any specific barrier to shifting focus from research and development to commercialization. This proposed finding is also vague to the extent that it does not define "success." [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

68. GRAIL is subject to numerous business and industry risks. For example:

Response to Finding No. 68

The proposed finding is vague because it does not define "numerous." [redacted] Therefore, this Court should disregard the proposed finding.

68.1 GRAIL is operating in a rapidly evolving field and has a limited operating history, which makes it difficult to evaluate GRAIL's current business and predict GRAIL's future performance. (PX0043 (GRAIL) at 11, 20; *see also* Bishop (GRAIL) Tr. 1414.)

Response to Finding No. 68.1

The proposed finding is vague because it does not define "rapidly evolving" or "limited operating history." [redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

68.2 GRAIL may not be successful in transitioning its products to a new or enhanced version or iteration, since product development involves a lengthy and complex process and GRAIL may be unable to commercialize, validate, or improve performance of any of its products on a timely basis, or at all. (PX0043 (GRAIL) at 11, 20; *see also* Bishop (GRAIL) Tr. 1415.)

Response to Finding No. 68.2

The proposed finding is vague because it does not define "commercialize," "validate," "improve performance," or "timely basis." [redacted] Therefore, this Court should disregard the proposed finding.

68.3 GRAIL has only limited sales and marketing infrastructures and no experience as a company in the sale, marketing, and distribution of screening or diagnostic tests. (PX0043 (GRAIL) at 35; *see also* Bishop (GRAIL) Tr. 1420–21.)

Response to Finding No. 68.3

[redacted]

[redacted]

68.4 Factors that may inhibit GRAIL's efforts to broadly commercialize any of its products include:

- GRAIL's inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to persuade adequate numbers of customers, including healthcare systems and healthcare providers, to use GRAIL's products;
- the inability to price GRAIL's products at a price point sufficient to ensure an adequate and attractive level of profitability;
- GRAIL's inability to effectively market to, collaborate with, and secure coverage and reimbursement from third-party payors;
- GRAIL's failure to comply with applicable regulatory requirements governing the sale, marketing, reimbursement, and commercialization of its products; and
- unforeseen costs and expenses associated with creating an independent commercial organization. (PX0043 (GRAIL) at 35; *see also* Bishop (GRAIL) Tr. 1420–21.)

Response to Finding No. 68.4

The proposed finding is vague because it does not define the terms "efforts to broadly commercialize," "adequate number of effective sales," "adequate number of customers," "adequate and attractive level of profitability," "applicable regulatory requirements," or "independent commercial organization." [redacted]

[redacted]

68.5 GRAIL is at a delicate and risky inflection point as it transitions from a company that up until recently was exclusively an R&D company; GRAIL will need to build different types of teams; serve customers; continue to develop technologies, including screening technologies and other new types of tests. (Bishop (GRAIL) Tr. 1367–68.)

Response to Finding No. 68.5

[redacted]

68.6 GRAIL has incurred significant net losses in each period since GRAIL's inception and anticipate that it will continue to incur net losses for the foreseeable future. (PX0043 (GRAIL) at 11, 20.)

Response to Finding No. 68.6

The proposed finding is vague because it does not define the terms "significant" or "foreseeable future." Therefore, this Court should disregard the proposed finding.

68.7 But for the Transaction, GRAIL may have failed to obtain additional financing and may be unable to expand its commercialization efforts with respect to Galleri and DAC and develop additional products. (PX0043 (GRAIL) at 29; Bishop (GRAIL) Tr. 1372; 1418; Freidin (GRAIL) Tr. 3052–53.)

Response to Finding No. 68.7

The proposed finding is unreliable because it relies upon the self-serving testimony of Grail executives. In addition, the proposed finding is unsupported because no evidence is cited to support the proposition that "but for the Transaction, GRAIL may have failed to obtain additional financing." [redacted] Therefore, this Court should disregard the proposed finding.

68.8 [redacted]

Response to Finding No. 68.8

[redacted]

68.9 Clinical trials are necessary to validate GRAIL's investigational products to launch them as LDTs and to support future product submissions to FDA. (PX0043 (GRAIL) at 11, 22.) The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. (PX0043 (GRAIL) at 11, 22; *see also* Aravanis (Illumina) Tr. 1878–80; PX7130 (Deverka Dep. at 72, 89, 92); *cf.* [redacted]

Response to Finding No. 68.9

[redacted]

[redacted]

68.10 GRAIL has encountered delays and may encounter substantial delays in its clinical studies, including due to COVID-19, and may therefore be unable to complete its clinical studies on the timelines it expects, if at all, which could materially and adversely impact its ability to launch its products and seek regulatory clearance or approval. (PX0043 (GRAIL) at 11, 22; [redacted] PX7104 (Aravanis (Illumina) Dep. at 75–76, 268–69); [redacted]

Response to Finding No. 68.10

[redacted]

68.11 GRAIL is building a new laboratory to ensure capacity to meet future demand and reduce the cost of its test; is investing in robotics and other improvements and will need to obtain regulatory approval for these processes. (Bishop (GRAIL) Tr. 1368–69.)

Response to Finding No. 68.11

The proposed finding is vague and misleading. The proposed finding is vague because the phrase "these processes" is ambiguous and undefined. Complaint Counsel does not disagree that Grail is undertaking the specific activities listed. Grail did not need to obtain regulatory approval to engage in the construction of a new laboratory, however, or to "invest" in robotics or other improvements. To the extent that the prosed finding suggests that Mr. Bishop testified to that effect, the proposed finding is misleading and mischaracterizes his testimony.

68.12 Even if GRAIL commercially launches its products, it may fail to achieve the degree of market acceptance necessary for commercial success. (PX0043 (GRAIL) at 11, 24; PX7066 (Freidin (GRAIL) IHT at 97).)

Response to Finding No. 68.12

The proposed finding is vague because it does not define "commercial success." In addition, the proposed finding is unreliable because it relies on the self-serving testimony of a Grail executive about Grail's ability to "achieve the degree of market acceptance necessary for commercial success." Therefore, this Court should disregard the proposed finding.

68.13 GRAIL has never generated revenue from product sales, does not expect any near-term revenue to offset its ongoing operating expenses, and may never be profitable. (PX0043 (GRAIL) at 11, 25–26; PX7069 (Bishop (GRAIL) IHT at 191); [redacted]

Response to Finding No. 68.13

[redacted]

68.14 GRAIL may be unable to develop and commercialize new products. (PX0043 (GRAIL) at 11, 26–27; *see also* Bishop (GRAIL) Tr. 1414–15.)

Response to Finding No. 68.14

The proposed finding is unreliable because it relies on the self-serving testimony of a Grail executive concerning Grail's ability to develop and commercialize new products. Moreover, this finding should be disregarded as inherently speculative given that there is no evidence cited to explain the basis for this opinion. Therefore, this Court should disregard the proposed finding.

68.15 One of the key elements of GRAIL's strategy is to expand access to GRAIL's tests by pursuing reimbursement and coverage from third-party payors. (PX0043 (GRAIL) at 27; *see also* Bishop (GRAIL) Tr. 1416–17.)

Response to Finding No. 68.15

Complaint Counsel does not disagree with the proposed finding.

68.16 If GRAIL's products do not receive adequate coverage and reimbursement from third-party payors, its ability to expand access to its tests beyond its initial sales channels and its overall commercial success will be limited. (PX0043 (GRAIL) at 27; Bishop (GRAIL) Tr. 1416–18.)

Response to Finding No. 68.16

The proposed finding is vague because it does not define "adequate coverage and reimbursement." In addition, the proposed finding is unreliable because it relies on the self-serving testimony of a Grail executive concerning Grail's overall commercial success. Therefore, this Court should disregard the proposed finding.

68.17 If GRAIL's competitors' products do not perform as intended, the market for GRAIL's products could be impaired. (PX0043 (GRAIL) at 28.)

Response to Finding No. 68.17

The proposed finding is vague because it does not define the terms "perform as intended" or "impaired." Moreover, this document is taken out of context. This document actually explains that if any test marketed or being developed "do not perform to expectations or cause harm or injury to patients" it may lower confidence in early disease detection and post-diagnosis tests in general it does not say how it will impact the MCED market generally. Finally, this proposed finding is misleading to the extent that it implies that Illumina will not have any incentive to foreclose Grail's rivals. Therefore, this Court should disregard the proposed finding.

69. GRAIL is subject to regulation and legal compliance risks. For example:

Response to Finding No. 69

The proposed finding is unsupported because no evidence is cited for the claim that Grail

is subject to regulation and legal compliance risks. Therefore, this Court should disregard the proposed finding.

> 69.1 GRAIL launched Galleri initially as an LDT. (PX0043 (GRAIL) at 41; *see also* Ofman (GRAIL) Tr. 3317, [redacted]; PX7108 (Freidin (GRAIL) Dep. at 96); PX7069 (Bishop (GRAIL) Dep. at 65).)

Response to Finding No. 69.1

Complaint Counsel has no specific response to this proposed finding.

> 69.2 If FDA were to end or modify its current policy of enforcement discretion on LDTs, or if Congress were to enact legislation that changes the current requirements for LDTs, GRAIL may no longer be able to market Galleri without FDA premarket approval, which could result in substantial costs and delays. (PX0043 (GRAIL) at 41; *see also* Ofman (GRAIL) Tr. 3317–20; *cf.* Bishop (GRAIL) Tr. 1323, 1345.)

Response to Finding No. 69.2

The proposed finding is unsupported and vague. First, it relies solely on a Grail SEC filing and the self-serving testimony of Grail's Chief Medical Officer Dr. Joshua Ofman and former CEO Hans Bishop to speculate about potential changes in FDA enforcement policy and Congressional legislation. Second, it does not specify how the FDA could modify its current policy of enforcement discretion or how Congressional legislation could change the current requirements for LDTs. Further, the term "substantial" is ambiguous; it is not clear what constitutes substantial costs and delays. The proposed finding is also vague because "costs and delays" is ambiguous; it is unclear what specifically would be delayed or what "costs" specifically would "result" from potential changes in FDA enforcement policy and Congressional legislation. Therefore, this Court should disregard the proposed finding.

> 69.3 The regulatory clearance or approval processes of FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and unpredictable. (PX0043 (GRAIL) at 43; *see also* Bishop (GRAIL) Tr. 1411); PX7069 (Bishop (GRAIL) IHT at 64–65); PX7048 (Klausner (GRAIL) IHT at 119–20); *cf.* [redacted]

Response to Finding No. 69.3

The proposed finding is vague because the terms "lengthy," "time-consuming," and "unpredictable" are ambiguous. The proposed finding also fails to specify any "comparable foreign regulatory authorities" and so it is unclear to what Respondents are referring. Therefore, this Court should disregard the proposed finding.

> 69.4 If GRAIL is ultimately unable to obtain any necessary or desirable regulatory approvals or clearances, or if such approvals or clearances are significantly delayed, its business will be substantially harmed. (PX0043 (GRAIL) at 43; PX7104 (Aravanis (Illumina) Dep. at 289); [redacted]

Response to Finding No. 69.4

The proposed finding is vague because the terms "significantly" and "substantially" are ambiguous; it is not clear what constitutes significant delays or substantial harm. Additionally, it does not specify which regulatory approvals or clearances could cause such delays nor how Grail's business would be harmed. Therefore, this Court should disregard the proposed finding.

> 69.5 GRAIL's multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. (PX0043 (GRAIL) at 21, 44; [redacted]) Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PX0043 (GRAIL) at 21, 44; [redacted]); PX7065 (Aravanis (Illumina) IHT at 177); Bishop (GRAIL) Tr. 1421.)

Response to Finding No. 69.5

The proposed finding is misleading to the extent that it implies Grail has little to no information about the requirements to obtain PMA from the FDA. [redacted]

[redacted]

The proposed finding is vague because the terms "novel and complex issues" and "timely basis" are ambiguous. Therefore, this Court should disregard the proposed finding.

> 69.6 GRAIL's use and disclosure of personal information, including individually identifiable health information, biologic samples and related data are subject to federal, state and foreign privacy and security regulation. (PX0043 (GRAIL) at 45.) Data privacy rules are evolving and new legislation concerning privacy and data use may limit GRAIL's ability to use such data and specimens. (PX0043 (GRAIL) at 45.) GRAIL's failure to comply with privacy and security requirements or to adequately secure such information could result in significant liability, administrative or governmental penalties, and/or reputational harm and, in turn, substantial harm to its business and results of operations. (PX0043 (GRAIL) at 45.)

Response to Finding No. 69.6

The proposed finding is vague because the terms "significant" and "substantial" are ambiguous; it is not clear what constitutes significant liability or substantial harm. Additionally, the proposed finding is unsupported because it relies solely on a Grail SEC filing to support factual statements related to changes in state, federal, and foreign regulations, legislations, and penalties. Therefore, this Court should disregard the proposed finding.

> 69.7 If GRAIL or its partners fail to comply with federal, state, and foreign laboratory and other applicable licensing and registration requirements, GRAIL could be prevented from performing its tests or experience disruptions to its business. (PX0043 (GRAIL) at 47; Ofman (GRAIL) Tr. 3317–18; PX7092 (Ofman (GRAIL) Dep. at 178–79); PX7069 (Bishop (GRAIL) Dep. at 196); *cf.* PX7104 (Aravanis (Illumina) Dep. at 74–76).)

Response to Finding No. 69.7

The proposed finding is vague to the extent that it does not specify who Grail's "partners" are or how Grail could be prevented from performing its tests or experience disruptions to its business. The proposed finding is also vague because the phrase "federal, state,

and foreign laboratory and other applicable licensing and registration requirements" is broad and ambiguous; it is unclear to which requirements Grail is referring. The proposed finding is also vague because the term "disruptions to its business" is ambiguous and undefined. Additionally, the proposed finding is unsupported because it relies solely on a Grail SEC filing and the testimony of Grail and Illumina executives for statements about the consequences of non-compliance with unspecified federal, state, and foreign licensing and registration requirements. This Court should disregard the proposed finding.

> 69.8 Any product for which GRAIL obtains regulatory clearance or approval will be subject to extensive ongoing regulatory requirements, and GRAIL may be subject to penalties if it or its partners fail to comply with regulatory requirements or if GRAIL experiences unanticipated problems with its products. (PX0043 (GRAIL) at 49.)

Response to Finding No. 69.8

The proposed finding is vague because it does not specify the regulatory clearances or approvals to which it is referring, what ongoing regulatory requirements would entail, and what penalties Grail might suffer if it or its partners fail to comply. It is also not clear who Grail's "partners" are. Additionally, the proposed finding is unsupported because it relies solely on a Grail SEC filing for statements about regulatory approvals, requirements, and penalties. Therefore, this Court should disregard the proposed finding.

> 69.9 To obtain and maintain FDA approvals or clearances, GRAIL's products will need to be manufactured in accordance with federal and state regulations, and it could be forced to recall its devices or terminate production if it or its partners fail to comply with these regulations. (PX0043 (GRAIL) at 50–51.)

Response to Finding No. 69.9

The proposed finding is vague because it is not clear who Grail's "partners" are. Additionally, the proposed finding is unsupported because it relies solely on a Grail SEC filing to speculate on federal and state regulations and penalties. Therefore, this Court should disregard the proposed finding.

69.10 Healthcare reform measures, including recently enacted legislation reforming the U.S. healthcare system, and data protection measures, could significantly harm GRAIL's business, operations and financial condition. (PX0043 (GRAIL) at 51.)

Response to Finding No. 69.10

The proposed finding is vague because the terms "healthcare reform measures," "legislation reforming the U.S. healthcare system," "data protection measures," and "significantly" are ambiguous and overly broad. The proposed finding fails to specify which recently enacted legislation, either at the federal, state, or local level, could harm Grail. Additionally, the proposed finding is unsupported because it relies solely on a Grail SEC filing for statements about healthcare reform and data protection measures. Therefore, this Court should disregard the proposed finding.

C. The Transaction

1. Overview

70. On September 21, 2020, Illumina and GRAIL announced they had entered into a definitive agreement under which Illumina would acquire GRAIL for cash and stock consideration of $8 billion upon closing of the transaction. (PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293; PX0378 (Illumina) at 3–4.)

Response to Finding No. 70

[redacted]

70.1 In addition, GRAIL stockholders were to receive future payments representing a tiered single digit percentage of certain GRAIL-related revenues.

(PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293; PX0378 (Illumina) at 3.)

Response to Finding No. 70.1

[redacted]

70.2 The Boards of Directors of Illumina and GRAIL approved the agreement. (PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293.)

Response to Finding No. 70.2

Complaint Counsel does not disagree with the proposed finding.

71. Under the terms of the agreement, at closing, GRAIL stockholders (including Illumina) were to receive total consideration of $8 billion, consisting of $3.5 billion in cash and $4.5 billion in shares of Illumina common stock, subject to a collar. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 2; PX0061 (Illumina) at 30.)

Response to Finding No. 71

Complaint Counsel does not disagree with the proposed finding, but notes for accuracy that Illumina closed the transaction in August 2021 (See CCFF ¶¶ 218-226).

71.1 Illumina currently holds 14.5% of GRAIL's shares outstanding, and approximately 12% on a fully diluted basis. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 3.)

Response to Finding No. 71.1

The proposed finding is incorrect. It states a fact as "currently" accurate but cites to documents dated September 21, 2020. Illumina closed the transaction in August 2021. (See CCFF ¶¶ 218-226). Therefore, this Court should disregard the proposed finding.

71.2 The collar on the stock consideration was to ensure that GRAIL stockholders excluding Illumina would receive a number of Illumina shares equal to approximately $4 billion in value if the 20 trading-day volume weighted average price of

Illumina stock as of 10 trading days prior to closing is between $295 and $399. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 2; RX3971 (Illumina) at 2, 294.)

Response to Finding No. 71.2

Complaint Counsel does not disagree with the proposed finding, but notes for accuracy that Illumina closed the transaction in August 2021 (See CCFF ¶¶ 218-226).

71.3 GRAIL stockholders excluding Illumina were to receive approximately 9.9 million Illumina shares if the 20 trading-day volume weighted average price of Illumina stock as of 10 trading days prior to closing was above $399 and approximately 13.4 million Illumina shares if the 20 trading-day volume weighted average price of Illumina stock as of 10 trading days prior to closing was below $295. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 294.)

Response to Finding No. 71.3

Complaint Counsel does not disagree with the proposed finding, but notes for accuracy that Illumina closed the transaction in August 2021 (See CCFF ¶¶ 218-226).

71.4 Upon closing of the transaction, current Illumina stockholders are expected to own approximately 93% of the combined company, while GRAIL stockholders are expected to own approximately 7% based on the mid-point of the collar. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 294.)

Response to Finding No. 71.4

Complaint Counsel does not disagree with the proposed finding, but notes for accuracy that Illumina closed the transaction in August 2021 (See CCFF ¶¶ 218-226).

72. In connection with the transaction, GRAIL stockholders were also to receive contingent value rights, which would entitle holders to receive future payments representing a pro rata portion of certain GRAIL-related revenues each year for a 12 year period. (PX0122 (Illumina) at 3; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 6; PX0061 (Illumina) at 66.)

Response to Finding No. 72

Complaint Counsel does not disagree with the proposed finding, but notes for accuracy that Illumina closed the transaction in August 2021 (See CCFF ¶¶ 218-226).

72.1 This will reflect a 2.5% payment right to the first $1 billion of revenue each year for 12 years. (PX0061 (Illumina) at 66). Revenue above $1 billion each year would be subject to a 9% contingent payment right during this same period. (PX0122

(Illumina) at 3; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 4, 143, 295; PX0061 (Illumina) at 5, 31, 36, 66.)

Response to Finding No. 72.1

Complaint Counsel does not disagree with the proposed finding, but notes for accuracy that Illumina closed the transaction in August 2021 (See CCFF ¶¶ 218-226).

72.2 Illumina offered GRAIL stockholders the option to receive additional cash and/or stock consideration, in an amount to be determined prior to closing, in lieu of the contingent value rights. (PX0122 (Illumina) at 3; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 2, 295; PX0061 (Illumina) at 36, 66.) Forty percent of shares outstanding have opted for the CVR Consideration. [redacted]

Response to Finding No. 72.2

[redacted]

2. **Strategic Benefits**

73. There are numerous strategic benefits of the transaction, including (1) saving of thousands of lives, (2) acceleration of market access to Galleri, (3) R&D efficiencies, (4) reduction of GRAIL's royalty burden, (5) elimination of double marginalization and (6) supply chain efficiencies, operational efficiencies and acceleration of international expansion of Galleri. (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3283–84; 3307–08; 3320–21; [redacted] Freidin (GRAIL) Tr. 2973–74; 2986, 2999, 3007–08.)

Response to Finding No. 73

[redacted]

[redacted]

[redacted]

[redacted]

3. **Consummation of the Deal**

74. On August 18, 2021, Illumina consummated the transaction, but committed to holding GRAIL as a separate company during the European Commission's ongoing regulatory review. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2234–38.)

Response to Finding No. 74

The proposed finding is misleading and incomplete. First, it does not acknowledge that Illumina's consummation of the transaction violated a standstill order from the European Commission. Illumina acknowledged in an SEC filing that "pursuant to Article 22(4) of the EU Merger Regulation, Illumina was prohibited from implementing the Acquisition (i) until the European Commission clears the Acquisition under the EU Merger Regulation or (ii) until the European Commission refuses the Referral, and therefore the European Commission's acceptance of the Referral continued the purported standstill on the completion of the Acquisition until such time as the European Commission completes its review and approves the Acquisition." (PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)). Illumina understood that consummating the transaction during the pendency of the European Commission's review could result in the imposition of "fines, penalties, remedies or restrictions" by regulatory authorities and "other adverse consequences to, among other things, its reputation[.]" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2235-37 (stating that Illumina decided to close the transaction despite the potential fines from the European Commission and the potential risk to its reputation)).

Second, the proposed finding does not acknowledge that despite Illumina's commitments to hold Grail as a separate company, shortly after the consummation Illumina [redacted]

[redacted]. In addition, shortly after Grail's CEO Hans Bishop testified at trial, Illumina announced that Bishop was stepping down as CEO and that Illumina's Chief Operations Officer, Bob Ragusa, would take his place. (PX0405, (Illumina Appoints Ragusa as Chief Executive Officer (CEO) of GRAIL, Oct. 14, 2021, https://www.illumina.com/company/newscenter/ press-releases/press-release-details.html?newsid=2e72344d-ceaf-4453-868a-423516a4ba49 (last visited Oct. 25, 2021)). At Illumina, Ragusa held $1 million in Illumina stock, [redacted] Therefore, this Court should disregard the proposed finding.

75. Regulators in the EU were still reviewing the transaction, but a decision was projected after the deal expires. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2235–38, 2475–77.)

Response to Finding No. 75

The proposed finding is misleading and incomplete because it does not acknowledge that Illumina's consummation of the transaction violated a standstill order from the European Commission. Illumina acknowledged in an SEC filing that "pursuant to Article 22(4) of the EU Merger Regulation, Illumina was prohibited from implementing the Acquisition (i) until the European Commission clears the Acquisition under the EU Merger Regulation or (ii) until the European Commission refuses the Referral, and therefore the European Commission's acceptance of the Referral continued the purported standstill on the completion of the Acquisition until such time as the European Commission completes its review and approves the Acquisition." (PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)). Illumina understood that consummating the transaction during the pendency of the European Commission's review could

result in the imposition of "fines, penalties, remedies or restrictions" by regulatory authorities and "other adverse consequences to, among other things, its reputation[.]" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2235-37 (stating that Illumina decided to close the transaction despite the potential fines from the European Commission and the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

76. GRAIL has no business in the EU, and Illumina believes that the European Commission does not have jurisdiction to review the merger as the EU merger thresholds are not met, nor are they met in any EU member state. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2235–38, 2339–40; PX0378 (Illumina) at 3–4.)

Response to Finding No. 76

The proposed finding is vague and unsupported. It relies solely on an Illumina press release, Illumina SEC filing, and the self-serving testimony of Illumina CEO Francis deSouza to claim that Grail has no business in the EU. The claim that the European Commission does not have jurisdiction to review the merger should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of Illumina's press release. (*See* PX0377 (Illumina Acquires GRAIL to Accelerate Patient Access to Life-Saving Multi-Cancer Early-Detection Test, Aug. 18, 2021)).

The proposed finding is vague because it does not specify which EU merger thresholds are not met. Therefore, this Court should disregard the proposed finding.

76.1 The General Court of the European Union is expected to decide Illumina's jurisdictional challenge some time in 2022. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2235–38, 2339–40; PX0378 (Illumina) at 4.)

Response to Finding No. 76.1

The proposed finding is vague because the term "some time" is ambiguous. Therefore,

this Court should disregard the proposed finding.

77. There was no legal impediment to Illumina acquiring GRAIL in the US. Illumina believes the reasons to reunite the two companies are compelling:

Response to Finding No. 77

The proposed finding is misleading, incomplete, and unsupported. It is unsupported because no evidence is cited for the claim that there was no legal impediment to Illumina acquiring Grail in the United States.

Additionally, the proposed finding is misleading and incomplete to the extent that it suggests Illumina could acquire Grail without the imposition of fines and penalties or a legal challenge from regulatory authorities. When Illumina consummated the transaction on August 18, 2021, it acknowledged that "Illumina was prohibited from implementing the Acquisition" during the "pendency of the European Commission's review," and that the transaction could result in the imposition of "fines, penalties, remedies or restrictions" by government or regulatory authorities. (PX0378 at 005, 004 (Illumina Form 8-K, Aug. 18, 2021)). Moreover, the FTC could still challenge Illumina and Grail in federal court. The FTC initially challenged the parties in federal court on March 31, 2021, when the FTC filed a Complaint for Preliminary Injunction and Temporary Restraining Order ("PI Complaint") to maintain the *status quo* and prevent Illumina and Grail from consummating the proposed transaction. On May 21, 2021, after the European Commission announced that it was opening an investigation into the proposed transaction, the FTC moved to voluntarily dismiss its PI Complaint without prejudice, understanding that Illumina and Grail would be prohibited from closing under the European Commission's merger regulations. In other words, the FTC's PI Complaint was no longer needed, at that time, to maintain the *status quo* pending administrative trial. (Plaintiff's Ex Parte Application to Dismiss Under Federal Rule of Civil Procedure 41(A)(2), *Federal Trade*

Commission v. Illumina, Inc and Grail, Inc., No. 3:21-cv-00800 (S.D. Cal) (May 21, 2021)). On May 28, 2021, the Court granted the FTC's motion to dismiss its PI Complaint without prejudice, meaning that the FTC could file a Complaint for Preliminary Injunction and Temporary Restraining Order at a later date, if necessary. ((Transcript of Motion Hearing Before the Honorable Cathy Ann Bencivengo, United States District Judge, *Federal Trade Commission v. Illumina, Inc and Grail, Inc.*, No. 3:21-cv-00800 (S.D. Cal) (May 28, 2021)). The FTC could, however, return to federal court if necessary to seek injunctive relief preventing Illumina and GRAIL from integrating their operations during the pendency of the administrative law proceeding in this Court. Therefore, this Court should disregard the proposed finding.

77.1 The deal will save lives. Cancer kills around 10 million people annually worldwide and 600,000 people in the US alone. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2372.)

Response to Finding No. 77.1

The proposed finding is unsupported and misleading. It relies solely on an Illumina press release and the self-serving testimony of Illumina CEO, Francis deSouza, to assert that the deal will save lives. Additionally, the proposed finding is misleading to the extent that it suggests the deal is necessary to save lives. [redacted] Therefore, this Court should disregard the proposed finding.

77.2 Cancers responsible for nearly 71% of cancer deaths have no recommended early detection screening, and most cancers are detected when chances of survival are lower. (PX0377 (Illumina) at 1; *cf.* Aravanis (Illumina) Tr. 1904.)

Response to Finding No. 77.2

The proposed finding is unsupported because it relies solely on an Illumina press release and the self-serving testimony of Illumina Senior Vice President and Chief Technology Officer,

Dr. Alex Aravanis, to establish statistics on cancer detection and deaths. It is not clear where this data came from or whether or how it was verified. Therefore, this Court should disregard the proposed finding.

> 77.3 Illumina believes there is a moral obligation to have the deal decided by a thoughtful and full review by the EU regulators and the US courts; this can only be done if Illumina acquires GRAIL now. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2339–40.)

Response to Finding No. 77.3

The proposed finding is vague, misleading, and unsupported. The claim that Illumina's acquisition of Grail is necessary for a full review by EU regulators and the US courts should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of Illumina's press release. (*See* PX0377 (Illumina Acquires GRAIL to Accelerate Patient Access to Life-Saving Multi-Cancer Early-Detection Test, Aug. 18, 2021)).

Furthermore, the proposed finding disregards the fact that Illumina's consummation of the transaction violated a standstill order from the European Commission, thereby interfering with a "thoughtful and full review" by the European Commission, the Federal Trade Commission, and the U.S. courts. Illumina acknowledged in an SEC filing that "pursuant to Article 22(4) of the EU Merger Regulation, Illumina was prohibited from implementing the Acquisition (i) until the European Commission clears the Acquisition under the EU Merger Regulation or (ii) until the European Commission refuses the Referral, and therefore the European Commission's acceptance of the Referral continued the purported standstill on the completion of the Acquisition until such time as the European Commission completes its review and approves the Acquisition." (PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)). Illumina

understood that consummating the transaction during the pendency of the European Commission's review could result in the imposition of "fines, penalties, remedies or restrictions" by regulatory authorities and "other adverse consequences to, among other things, its reputation[.]" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2235-37 (stating that Illumina decided to close the transaction despite the potential fines from the European Commission and the potential risk to its reputation)).

Additionally, the proposed finding is vague because the term "moral obligation" is ambiguous. Therefore, this Court should disregard the proposed finding.

> 77.4 Otherwise, the company is locked into a situation where the deal terms will expire before there is a chance for full review; the clock will just run out. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2475–77.)

Response to Finding No. 77.4

The proposed finding is vague and misleading. It is unclear what "otherwise" refers to, and the terms "situation," "deal terms," and "the clock" are ambiguous.

Additionally, the proposed finding disregards the fact that Illumina's consummation of the transaction violated a standstill order from the European Commission, thereby interfering with the Commission's "full review." Illumina acknowledged in an SEC filing that "pursuant to Article 22(4) of the EU Merger Regulation, Illumina was prohibited from implementing the Acquisition (i) until the European Commission clears the Acquisition under the EU Merger Regulation or (ii) until the European Commission refuses the Referral, and therefore the European Commission's acceptance of the Referral continued the purported standstill on the completion of the Acquisition until such time as the European Commission completes its review and approves the Acquisition." (PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)). Illumina understood that consummating the transaction during the pendency of the European Commission's review could result in the imposition of "fines, penalties, remedies or restrictions"

by regulatory authorities and "other adverse consequences to, among other things, its reputation[.]" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2235-37 (stating that Illumina decided to close the transaction despite the potential fines from the European Commission and the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

77.5 Right now, the Galleri test is available but costs $950 because it is not covered by insurance. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2342.)

Response to Finding No. 77.5

The proposed finding is confusing because it claims Galleri costs $950 "because" it is not covered by insurance. The proposed finding is vague because it implies that Galleri would "cost" less if it were covered by insurance, but does not explain for whom the cost would purportedly be lower or why. Therefore, this Court should disregard the proposed finding.

77.6 Reuniting the two companies is the fastest way to make the test broadly available and affordable. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2341–43.)

Response to Finding No. 77.6

The proposed finding is misleading and unsupported. It relies solely on an Illumina press release and the self-serving testimony of Illumina CEO, Francis deSouza, to assert that reuniting the two companies is the fastest way to make the test broadly available and affordable. Additionally, the proposed finding is misleading to the extent that it suggests the deal is necessary to make Galleri broadly available and affordable. [redacted] Therefore, this Court should disregard the proposed finding.

77.7 Illumina's expertise in market development and access has resulted in coverage of genomic testing for over 1 billion people around the world already. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2342–43.)

Response to Finding No. 77.7

The proposed finding is vague because the terms "market development and access," "expertise," and "coverage of genomic testing" are ambiguous. The proposed finding is unsupported because it relies solely on an Illumina press release and the self-serving testimony of Illumina CEO, Francis deSouza, to assert that Illumina's purported expertise has resulted in coverage for over 1 billion people. Therefore, this Court should disregard the proposed finding.

77.8 This experience will help lead to coverage and reimbursement for the Galleri test. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2341–43.)

Response to Finding No. 77.8

The proposed finding is vague and misleading. It is unclear what the term "this experience" refers to. Additionally, the proposed finding is misleading to the extent that it suggests that the deal is necessary for Galleri coverage and reimbursement. [redacted] Therefore, this Court should disregard the proposed finding.

77.9 GRAIL and Illumina have a long history. Illumina formed GRAIL and spun it out in 2016. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2195–96.)

Response to Finding No. 77.9

The proposed finding is vague because the term "long history" is ambiguous. Otherwise, Complaint Counsel has no specific response to this proposed finding.

77.10 GRAIL's first employees were part of Illumina, which still owns 12 percent of the company. (PX0377 (Illumina) at 2; *see also* Flatley (Illumina) Tr. 4094; [redacted] 152–53, [redacted]).)

Response to Finding No. 77.10

[redacted]

77.11 GRAIL and Illumina are not competitors. (PX0377 (Illumina) at 2; PX7073 (Aravanis (Illumina) IHT at 80).)

Response to Finding No. 77.11

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of Illumina's press release that is solely supported by the self-serving testimony of Illumina Senior Vice President and Chief Technology Officer, Dr. Alex Aravanis. (*See* PX0377 (Illumina Acquires GRAIL to Accelerate Patient Access to Life-Saving Multi-Cancer Early-Detection Test, Aug. 18, 2021)).

77.12 Based on past experience, when Illumina enters a market, the market expands. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2392–94.) When Illumina entered the non-invasive prenatal testing space, prices dropped, reimbursement expanded, the number of providers increased, and more expectant parents had access to testing. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2392–94.)

Response to Finding No. 77.12

[redacted]

[redacted]

[redacted]

77.13 Illumina's acquisition of GRAIL is driven by the belief that Galleri should be available to as many people as possible as quickly as possible. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2342.) From fighting the COVID-19 pandemic to matching cancer patients to therapies, Illumina's mandate is to save lives and transform healthcare. (PX0377 (Illumina) at 2.)

Response to Finding No. 77.13

The proposed finding is misleading to the extent that it suggests Illumina's acquisition of Grail is necessary for Galleri to be available to as many people as possible as quickly as possible.

[redacted]

The proposed finding is misleading to the extent that it implies Illumina prioritizes "sav[ing] lives and transform[ing] healthcare" over making as much money as possible. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it only makes business sense for Illumina to "save lives and transform healthcare" if that is a byproduct of increasing its revenues. Therefore, this Court should disregard the proposed finding.

II. BACKGROUND

A. Oncology Overview

1. Cancer and Cancer Stages

78. Cancer affects one in three people in the United States. (RX3035 (ACS) at 1.) As the second leading cause of death in the U.S., behind only heart disease, cancer leads to one in every four deaths in the U.S. (RX3103 (CDC); *see also* Cote Tr. 3728–29.)

Response to Finding No. 78

Complaint Counsel does not disagree with the proposed finding.

79. Cancer has been found in all organs of the human body and is typically named for the part of the body where the cancer originated. (*See* RX3103 (CDC); RX3035 (ACS).)

Response to Finding No. 79

Complaint Counsel does not disagree with the proposed finding.

80. Breast, prostate, lung, and colorectal are the most common cancer types. (RX3103 (CDC).)

Response to Finding No. 80

Complaint Counsel does not disagree with the proposed finding.

81. Cancer is characterized by the development of abnormal cells that divide uncontrollably. (RX3449 (Mayo Clinic) at 2; RX3869 (Cote Expert Report) ¶ 26). Cancers are understood to be caused by accumulated changes or mutations to the DNA inside cells. (RX3449 (Mayo Clinic) at 1–2; RX3869 (Cote Expert Report) ¶ 26.)

Response to Finding No. 81

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

81.1 Often these changes are to genes that control cellular functions, such as those controlling cell growth and division, or DNA repair. (RX3449 (Mayo Clinic) at 1–2.)

Response to Finding No. 81.1

Complaint Counsel has no specific response to the proposed finding.

82. Increasing evidence suggests that cancer may be caused by genomic and epigenomic changes to DNA, including DNA methylation. (RX3401 (Kamel and Bagader Al-Amodi 2016) at 3; Cote Tr. 3733.)

Response to Finding No. 82

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

82.1 Such changes may be inherited from our parents, or may be accumulated as a result of various factors, including from improper DNA repair and from the environment, such as exposure to smoking, radiation, viruses, and carcinogens. (RX3449 (Mayo Clinic) at 2; (RX3506 (National Cancer Institute) at 3; RX3869 (Cote Expert Report) ¶ 26.)

Response to Finding No. 82.1

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

83. DNA stands for deoxyribonucleic acid and is a molecule made up of four chemical bases: adenine, guanine, cytosine and thymine, abbreviated A, G, C and T. Each of these bases are known as "nucleotides"; RNA stands for ribonucleic acid, which comprises uracil, abbreviated U, instead of thymine; together, DNA and RNA are referred to as "nucleic acids." (Cote Tr. 3736; PX7131 (Cote Dep. at 137–138); RX3869 (Cote Expert Report) ¶ 26, n.21.)

Response to Finding No. 83

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed finding.

84. As a result of the genomic and epigenomic changes to the DNA, cancer cells differ from normal cells in that they undergo rapid and uncontrolled growth. (RX3449 (Mayo Clinic) at 2.) Such uncontrolled growth leads to the formation of tumors. (RX3869 (Cote Expert Report) ¶ 27; *see also* RX3449 (Mayo Clinic).)

Response to Finding No. 84

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

85. As these abnormal cells continue to grow and divide, cancer cells may spread (metastasize) to other parts of the body from where the cancer originated. (RX3449 (Mayo Clinic) at 4; RX3869 (Cote Expert Report) ¶ 27.)

Response to Finding No. 85

Complaint Counsel objects to the proposed finding because it is vague, unsupported, and improperly cites expert testimony.

The proposed finding is vague because "these abnormal cells" is not defined.

The proposed finding is unsupported because there is nothing in the cited source (RX3449 at 4) that discusses either cell division and growth or cancer cells spreading.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

86. As cancers progress, the cancer cells can enter the blood stream and the lymphatic system (lymph nodes), in a process called "metastasis". (RX3869 (Cote Expert Report) ¶ 27; RX3506 (National Cancer Institute).)

Response to Finding No. 86

Complaint Counsel objects to the proposed finding because it is incorrect and improperly cites expert testimony.

The proposed finding is incorrect because "metastasis" is actually defined in the cited

source as the "process by which cancer cells spread to other parts of the body," not the mere entry of cancer cells into the blood stream and lymphatic system. (RX3506 (National Cancer Institute) at 14). More specifically, "in metastasis, cancer cells break away from where they first formed (primary cancer), travel through the blood or lymph system, and form new tumors (metastatic tumors) in other parts of the body." (RX3506 (National Cancer Institute) at 14).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

87. As cancer cells first enter the blood, they are called circulating tumor cells ("CTC"); as these CTC enter other organs and grow, they form metastases, which is the major cause of cancer death. (Cote Tr. 3733; PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 27.)

Response to Finding No. 87

Complaint Counsel objects to the proposed finding because it is incorrect and improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed finding.

88. The American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) maintain the TNM (Tumor, Node, Metastasis) classification system, which characterizes the tumor by size and amount of spread into nearby tissue, its spread into lymph nodes, and metastatic status. (RX3031 (ACS); Cote Tr. 3730–33; RX3869 (Cote Expert Report) ¶ 28, n.25.)

Response to Finding No. 88

Complaint Counsel objects to the proposed finding because it is incorrect and improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

89. Stages of cancers are determined based on how much cancer there is in a patient's body and where it's located. (RX3031 (ACS) at 1; (Cote Tr. 3730–3732; RX3869 (Cote Expert Report) ¶ 28.) Cancer is commonly divided into five stages:

Response to Finding No. 89

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

89.1 Stage 0 can also refer to a cancer that has not yet invaded into surrounding normal tissue, which is also called carcinoma in *situ*. (Cote Tr. 3730–31; RX3869 (Cote Expert Report) ¶ 28.) Stage 0 can also refer to when a cancer has been treated prior to surgical removal (neoadjuvant therapy) and that cancer can no longer be found. (Cote Tr. 3730–31; RX3869 (Cote Expert Report) ¶ 28, n.26.)

Response to Finding No. 89.1

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed

finding.

89.2 Stage I, which is also called early-stage cancer, means there is cancer present, but it is small and only in one area, where the cancer originated. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 28.)

Response to Finding No. 89.2

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed finding.

89.3 Stage II is still an early stage cancer, but the cancer is larger, and it may also have metastasized to regional lymph nodes. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 28.)

Response to Finding No. 89.3

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed finding.

89.4 Stage III means the cancer is larger, has penetrated more deeply in to the organ of origin, and has spread to lymph nodes. (Cote Tr. 3730–32; RX3869 (Cote Expert Report) ¶ 28.)

Response to Finding No. 89.4

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed finding.

89.5 Stage IV, which is also called advanced or metastatic cancer, means the cancer has spread (metastasized) to other parts of the body. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 28.)

Response to Finding No. 89.5

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed finding.

90. At its earliest stages, particularly Stages 0, I and II, cancer generally does not cause symptoms. (RX3869 (Cote Expert Report) ¶ 29; *see also* Cote Tr. 3730–3732.) By the time symptoms develop, the cancer has very often progressed to Stages III or IV. (RX3869 (Cote Expert Report) ¶ 29; *see also* Cote Tr. 3730–30.)

Response to Finding No. 90

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual proposition that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported. Therefore, this Court should disregard the proposed finding.

91. Cancer staging also helps oncologists determine the best treatment options, such as surgery, radiation, chemotherapy, targeted drug therapy, and immunotherapy, many of which are either invasive, or cause significant harm to normal cells in the body. (RX3031 (American Cancer Society, Cancer Staging) at 1; RX3869 (Cote Expert Report) ¶ 30.)

Response to Finding No. 91

Complaint Counsel objects to the proposed finding because it is unsupported and improperly cites expert testimony.

The proposed finding is unsupported because there is nothing in the cited source (RX3031 at 1) that discusses either cancer treatment options or their effects.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

92. The earlier a cancer can be detected, the higher the cure rate. [redacted]; Cance (ACS) Tr. 600–01, 606–08; PX7086 (Cance (ACS) Dep. at 81, 97) RX3869 (Cote Expert Report) ¶ 31.) Because of this, detecting cancer at earlier stages has been the focus of intense research by the scientific community. [redacted]; Cote Tr. 3719–21; RX3869 (Cote Expert Report) ¶ 31.)

Response to Finding No. 92

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 92.1 Depending on the type of cancer, patients with Stage 0, I and II cancers can often be cured by surgery alone, or by a combination of surgery and other therapies, such as chemo- or radiation therapy. (Cote Tr. 3731–32; RX3869 (Cote Expert Report) ¶ 31). Stage III cancer has a much lower cure rate. (Cote Tr. 3731–32; RX3869 (Cote Expert Report) ¶ 31).

Response to Finding No. 92.1

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 92.2 While Stage IV cancer may be treated (resulting in prolongation of life), it is almost always incurable and will eventually result in the death of the patient. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 31.) Patients diagnosed with Stage IV cancer only account for approximately 18% of total cancer cases, but represent up to 48% of deaths caused by cancer within five years of diagnosis. (RX3178 (Hubbell et al., 2020) at 1.)

Response to Finding No. 92.2

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

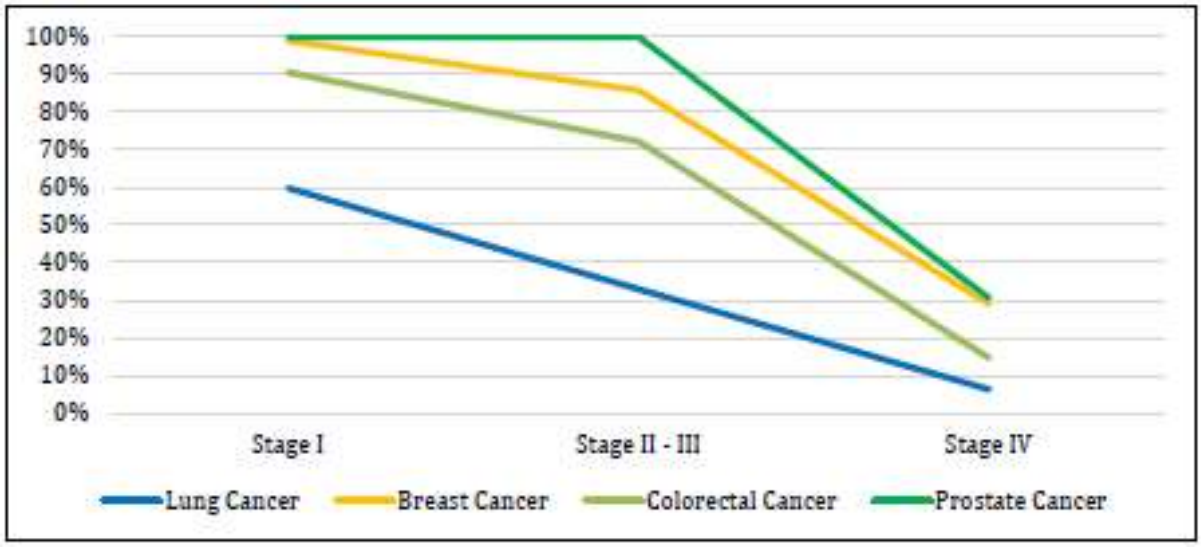
93. Epidemiologically speaking, a cancer patient's survival rates and prognosis correlates to the stage of cancer at the time of the diagnosis. (Cote Tr. 3730–32; RX3869 (Cote Expert Report) ¶ 32.) That is, the earlier the cancer is detected, the higher the likelihood that the patient will recover from cancer, and the longer the patient is likely to survive after the diagnosis. [redacted]; Cance (ACS) Tr. 600–01, 606–08; PX7086 (Cance (ACS) Dep. at 81, 97; Cote Tr. 3730–32; RX3869 (Cote Expert Report) ¶ 32.)

Response to Finding No. 93

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 93.1 In breast, colorectal, and prostate cancer, patients diagnosed at Stages I–III have average five-year survival rates between 70% and nearly 100%, while patients with the same types of cancer who are diagnosed at Stage IV experience five-year survival rates of only 14-30%. (RX3504 (SEER) at 4–5; RX3503 (SEER) at 4–5; RX3505 (SEER) at 4–5; RX3869 (Cote Expert Report) ¶ 32.)

Figure 2: Five-Year Survival Correlated With Stage At Diagnosis



(RX3869 (Cote Expert Report) Figure 1.)

Response to Finding No. 93.1

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should

disregard this evidence and the proposed finding.

94. It is well understood that the rate of death for certain cancers, in particular breast, prostate, lung and colon cancer, has declined over the past few decades in the U.S. (RX3033 (ACS) at 2.) This is almost entirely due to earlier detection of these tumor types by routine screening. (RX3869 (Cote Expert Report) ¶ 32; *see also* RX3033 (ACS) at 2.)

Response to Finding No. 94

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

95. For tumors that do not have effective screening technologies, such as pancreas, ovary and stomach cancers (to name a few), the rate of death has been largely unaffected, even in the face of advanced therapies. (PX0125 (ACS) at 4, Figure 1, 20, Table 7; RX3869 (Cote Expert Report) ¶ 32.)

Response to Finding No. 95

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

96. Most types of cancers do not currently have effective *screening* technologies, again highlighting the need for better methods of early detection. [redacted]; Cote Tr. 3728–3729; RX3869 (Cote Expert Report) ¶ 32.)

Response to Finding No. 96

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

2. **Biomarkers for Cancer Testing**

97. Currently, many companies and academic groups are researching methods for early cancer screening. [redacted]; Cote Tr. 3719–21; RX3869 (Cote Expert Report) ¶ 33.) Many of these methods detect biomarkers that indicate or suggest the presence of cancer. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 33.)

Response to Finding No. 97

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

98. As a result of the accumulated genomic and/or epigenomic changes in the cancer cells, these cells exhibit uncontrolled cell division and proliferation as well as inhibited apoptosis (cell death). (RX3449 (Mayo Clinic) at 2; PX7131 (Cote Dep. at 60); RX3869 (Cote Expert Report) ¶ 34.)

Response to Finding No. 98

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

99. Such uncontrolled cell division and proliferation result in further genomic and epigenomic changes to the cancer cells. (RX3449 (Mayo Clinic) at 2); PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 34.)

Response to Finding No. 99

Complaint Counsel objects to the proposed finding because it is vague and it improperly

cites expert testimony.

The proposed finding is vague because "such uncontrolled cell division and proliferation" is undefined.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

100. As cancer cells grow and die, they release their contents, including DNA, RNA, proteins and metabolites into the blood and sometimes other body fluids, such as urine, saliva and sputum. (RX3401 (Kamel, Cancer Biomarkers); Cote Tr. 3733; PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 39.)

Response to Finding No. 100

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

101. These released cellular constituents, also called "biomarkers", can be detected by various technologies, and have been the source of intense scientific focus due to their potential to help diagnose cancer earlier, at a more curable stage. (RX3401 (Kamel, Cancer Biomarkers) at 1; Cote Tr. 3733; PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 39.)

Response to Finding No. 101

Complaint Counsel objects to the proposed finding because it is vague, misleading, and it improperly cites expert testimony.

The proposed finding is vague because "these released cellular constituents" is undefined.

The proposed finding is also vague because it does not define "various technologies" and is misleading because it suggests that MCED testing can be accomplished without using Illumina

NGS.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

102. Similarly, exosomes and their constituent components may also be used as a biomarkers for cancer patients. (RX3165 (Dai, Exosomes: Key Players in Cancer and Potential Therapeutic Strategy) at 2; PX7131 (Cote Dep. at 111–12); RX3869 (Cote Expert Report) ¶ 39.)

Response to Finding No. 102

Complaint Counsel objects to the proposed finding because it is vague, misleading, and improperly cites expert testimony.

The proposed finding is vague because it does not define "exosomes" and does not explain what "used as biomarkers for cancer patients" means.

The proposed finding is misleading because it suggests "exosomes and their constituent components" may be used as biomarkers for MCED testing, which is not supported by the source cited (RX3165).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

103. Many tests in routine use today may be used to detect cancer biomarkers. (RX3869 (Cote Expert Report) ¶ 40). Detection of cancer biomarkers is commonly used to help screen for early stage cancer, for example, detection of Prostate Specific Antigen ("PSA") in the blood for prostate cancer. (Cance (ACS) Tr. 606–07, 622–23; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 40.)

Response to Finding No. 103

Complaint Counsel objects to the proposed finding because it is vague, misleading, and

improperly cites expert testimony.

The proposed finding is vague because it does not specify or define the purported "many tests in routine use today" and does not define "detect."

The proposed finding is misleading to the extent it suggests that protein biomarkers such as Prostate Specific Antigen are alone sufficient for MCED testing.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

104. Cancer biomarkers are often used for other applications, such as helping determine specific treatments to which a cancer is likely to respond (*i.e.*, cancer therapy selection), by following the course of cancer therapy to see if the therapy is working, and to help detect recurrence of cancer. (Cote Tr. 3733, 3735–36; RX3869 (Cote Expert Report) ¶ 40.)

Response to Finding No. 104

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

105. Cancer biomarkers are most often a very small portion of the DNA, RNA, proteins and metabolites that can be found in the blood and other body fluids. (PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 41.)

Response to Finding No. 105

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague and imprecise because it does not define what "a very

small portion" means.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

106. This is particularly true when cancer is at its earliest, most curable stages, because the total amount of cancer cells in the body at these stages is very small. (PX7131 (Cote Dep. at 59); Cote Tr. 3734–36; RX3869 (Cote Expert Report) ¶ 41.) Thus, detection of biomarkers that indicate the presence of an early stage, potentially curable cancer, has been technically very challenging. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 41.)

Response to Finding No. 106

Complaint Counsel objects to the proposed finding because it is vague, misleading, and it improperly cites expert testimony.

The proposed finding is vague because the first subject, "[t]his" is undefined. It is also vague because it does not define "technically very challenging."

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

a. DNA Biomarkers

107. DNA biomarkers, also called *genomic* biomarkers, are among the most common biomarkers for cancer used by researchers and test developers today. (RX3869 (Cote Expert Report) ¶ 42.) DNA biomarkers from cancer cells may be identified in various types of samples from a cancer patient. [redacted]; Cance (ACS) Tr. 609–10; RX3869 (Cote Expert Report) ¶ 42.)

Response to Finding No. 107

[redacted]

107.1 DNA biomarkers may be extracted and evaluated directly from tissue biopsy samples. (RX3869 (Cote Expert Report) ¶ 43). DNA biomarkers may also be found in bodily fluids, such as blood, urine, saliva and sputum samples. (Cance (ACS) Tr. 609–10; RX3869 (Cote Expert Report) ¶ 43).

Response to Finding No. 107.1

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

107.2 DNA biomarkers obtained from blood and other body fluids are known as cell-free DNA ("cfDNA") and more specifically, when detected in the blood, where they are known as circulating tumor DNA ("ctDNA"). (Cance (ACS) Tr. 609; RX3869 (Cote Expert Report) ¶ 43.)

Response to Finding No. 107.2

Complaint Counsel objects to the proposed finding because it is confusing, incorrect, and improperly cites expert testimony.

The proposed finding is confusing because it claims that DNA biomarkers "are known

as" cell-free DNA and "circulating tumor DNA." This is not correct. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 107.3 DNA biomarkers may be used to identify both genomic and epigenomic changes that may be relevant for cancer. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 44.) Genomic changes include gene mutations, amplifications, and chromosomal rearrangements. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 44.)

Response to Finding No. 107.3

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague and imprecise because it does not specify or define what "may be relevant for cancer" means.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 107.4 Epigenomic changes are those things that occur to specific DNA molecules, or to proteins that regulate DNA function, but are not structural changes in the DNA sequence or copy number, and include histone modifications and DNA methylation. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 45.)

Response to Finding No. 107.4

Complaint Counsel objects to the proposed finding because it is vague and it improperly cites expert testimony.

The proposed finding is vague because it does not define or explain what is meant by "those things."

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

107.5 These epigenomic changes have been of intense interest in the scientific community, and are now believed to be crucial in cancer formation and progression. [redacted]; Cance (ACS) Tr. 612–13; Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 45.)

Response to Finding No. 107.5

[redacted]

108. Many technologies have been used to detect these genomic and epigenomic changes in cancer DNA biomarkers (including DNA methylation), including polymerase chain reaction ("PCR"), sequencing (such as next-generation sequencing), and microarray, as well as fluorescence *in situ* hybridization ("FISH"). (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 46.)

Response to Finding No. 108

Complaint Counsel objects to the proposed finding because it is vague, misleading, unsupported, and against the weight of the evidence, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because it does not identify any of the other purported "many technologies" referenced. The proposed finding is also vague because it does not explain or define what "these genomic and epigenomic changes in cancer DNA biomarkers (including DNA methylation)" refers to.

The proposed finding is misleading because it is not specific to MCED testing. The fact that PCR, micorarrays, FISH, or Sanger sequencing have purportedly been used in some limited way "to detect genomic and epigenomic changes in cancer DNA biomarkers" is not evidence that any of these technologies could be used *in the application of multi-cancer early detection*.

The proposed finding is unsupported because, other than the text of this purported fact, which was copied and pasted verbatim from Dr. Cote's report, there is no other information whatsoever in ¶ 46 or anywhere else in Dr. Cote's report even explaining to the Court what FISH is or how it has been used in any type of cancer-related application. The proposed finding is also misleading because there is no evidence in Dr. Cote's report that FISH ever has been or could be used for liquid biopsy-based MCED testing.

[redacted]

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and disregard the proposed finding.

b. RNA Biomarkers

109. RNA biomarkers are another type of biomarker, which are also called *transcriptomic* biomarkers. [redacted]; Cance (ACS) Tr. 609; Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 47.)

Response to Finding No. 109

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

110. As with DNA biomarkers, RNA biomarkers may also be extracted and evaluated from tissue and liquid biopsy samples. (RX3869 (Cote Expert Report) ¶ 48.) As with ctDNA and cfDNA, bodily fluids may contain circulating cell free RNA ("cfRNA"), which in individuals

with cancer, may contain circulating tumor RNA ("ctRNA"). (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 48.)

Response to Finding No. 110

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

111. Often, the genomic and epigenomic changes to the DNA in cancer cells may be reflected in the RNA biomarkers. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 48.)

Response to Finding No. 111

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because "often" is not specified.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

112. As with DNA biomarkers, many technologies have been used to detect the genomic and epigenomic changes in cancer RNA biomarkers. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 49).

Response to Finding No. 112

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because it does not identify any of the other purported

"many technologies" referenced. The proposed finding is also vague because it does not explain or define what "the genomic and epigenomic changes in cancer RNA biomarkers" refers to.

The proposed finding is misleading because it is not specific to MCED testing. The fact that "many technologies" have purportedly been used in some limited way "to detect genomic and epigenomic changes in cancer RNA biomarkers" is not evidence that any of these (unidentified) technologies could be used in the application of multi-cancer early detection.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

This Court should not accord Dr. Cote's opinion any weight and disregard the proposed finding.

113. Such changes in RNA biomarkers may be detected directly using microarray, RNA *in situ* hybridization ("RNA ISH") and circulating cancer cell RNA imaging. (Cote Tr. 3736–3737; RX3869 (Cote Expert Report) ¶ 49).

Response to Finding No. 113

Complaint Counsel objects to the proposed finding because it is vague, misleading, unsupported, against the weight of the evidence, and improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because it does not specify what "such changes" refers to.

The proposed finding is misleading because it is not specific to MCED testing. The fact that micorarrays, RNA ISH, or circulating cancer cell RNA imaging have purportedly been used in some limited way "to detect such changes in RNA biomarkers" is not evidence that any of these technologies could be used *in the application of multi-cancer early detection*.

The proposed finding is unsupported because, other than the text of this purported fact, which was copied and pasted verbatim from Dr. Cote's report, there is no other information whatsoever in ¶ 46 or anywhere else in Dr. Cote's report even explaining to the Court what RNA ISH or circulating cancer cell RNA imaging are or how either has been used in any type of cancer-related application. The proposed finding is also misleading because there is no evidence in Dr. Cote's report that either RNA ISH or circulating cancer cell RNA imaging ever has been or could be used for liquid biopsy-based MCED testing.

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

114. Alternatively, messenger RNAs ("mRNAs") may be first reverse-transcribed into complementary DNA ("cDNA"), and then the genomic and epigenomic changes may be detected using the same methods for DNA biomarkers, such as RT-PCR, and sequencing. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 49.)

Response to Finding No. 114

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because though the finding begins by stating "alternatively," the purported alternative is never specified or explained.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 114.1 The epigenomic changes like methylation to DNA and RNA may be directly detected by Oxford Nanopore's nanopore sequencers or indirectly detected by short-read sequencers using a method like bisulfite conversion. (Cote Tr. 3753–54; PX7131 (Cote Dep. at 124–26, 205–06); RX3869 (Cote Expert Report) ¶ 49 n.38.)

Response to Finding No. 114.1

Complaint Counsel objects to the proposed finding because it is misleading, against the weight of the evidence, and it improperly cites expert testimony.

The proposed finding is misleading to the extent it suggests that ONT's sequencing platform is feasible for MCED testing. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 114.2 Bisulfite conversion is a process in which potentially methylated DNA is treated with sodium bisulfite, leading to conversion of unmethylated cytosines (C) into uracils (U), while methylated cytosines (both 5–methylcytosine and 5–hydroxymethylcytosine) remain unchanged, thus allowing determination of DNA methylation at the singe nucleotide level. (Cote Tr. 3745; RX3869 (Cote Expert Report) ¶ 49 n.38.)

Response to Finding No. 114.2

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

114.3 Another non-bisulfite method to determine DNA methylation has also been developed. (RX3431 (Liu et al., 2019) at 2–3; RX3869 (Cote Expert Report) ¶ 49, n.38.)

Response to Finding No. 114.3

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed fact is vague because it does not specify or explain this other "non-bisulfite method."

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

c. Protein Biomarkers

115. Protein biomarkers, also called *proteomic* biomarkers, are also commonly used as cancer biomarkers. (Cance (ACS) Tr. 612–13, 632; Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 51.)

Response to Finding No. 115

Complaint Counsel objects to the proposed finding because it is misleading, against the weight of the evidence, and it improperly cites expert testimony.

The proposed finding is misleading to the extent it suggests that proteomics alone is

sufficient for MCED testing. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

116. Some of the genomic and epigenomic changes to the DNA in cancer cells can be reflected in the protein biomarkers, such as point mutations, truncations, fusions, loss of functions, and in the levels, or presence/absence, of protein biomarkers. (RX3869 (Cote Expert Report) ¶ 52).

Response to Finding No. 116

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

117. Protein biomarkers may be examined in bodily fluids, or at a cell, tissue, organ, system, or the whole-body level. (Cance (ACS) Tr. 632; Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 52.)

Response to Finding No. 117

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

118. The approach of using protein biomarker signatures for cancer early screening is an active area of academic and commercial interest, and studies have already determined that by using combinations of protein biomarkers, early cancer can be detected. (RX3274 (Gorelik et al., 2005) at 3; RX3412 (Kozak et al., 2003) at 1; RX3466 (Mor et al., 2005) at 1; Cote Tr. 3735–37.)

Response to Finding No. 118

Complaint Counsel objects to the proposed finding because it is vague, misleading, against the weight of the evidence, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because it does explain what "active area of academic and commercial interest" means.

The proposed finding is misleading because it is not specific to MCED testing. The Gorelik et al. paper from seventeen years ago (RX3274 (Gorelik et al., 2005) at 1, 4), the nearly twenty-year-old Kozak et al. paper (RX3412 (Kozak et al., 2003) at 1), and the Mor et al. paper from seventeen years ago (RX3466 (Mor et al., 2005) at 1) were all about single cancer detection, not multi-cancer early detection, were all about the same single cancer type (ovarian), and were all mere case-control studies. The proposed finding is also misleading because the cited papers did not establish the detection of early stage cancer in a true screening setting (i.e., in asymptomatic, undiagnosed patients not previously known or suspected of having cancer). These sources simply do not support that protein biomarkers alone can support the application of multi-cancer early detection (or even single-cancer early detection).

[redacted]

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 53), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and disregard the proposed finding.

119. Protein biomarkers are often used for following the course of treatment for patients with higher stage cancer, and to detect for recurrence in patients who have been treated for cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 53.)

Response to Finding No. 119

Complaint Counsel objects to the proposed finding because it is misleading, against the weight of the evidence, and it improperly cites expert testimony.

The proposed finding is misleading to the extent it suggests that proteomics alone is sufficient for MCED testing. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

d. Metabolite Biomarkers

120. Metabolite biomarkers, also called *metabolomic* biomarkers, are presently used less frequently than DNA, RNA and protein biomarkers. (RX3869 (Cote Expert Report) ¶ 54). Metabolite biomarkers are direct representations of cancer phenotypes and how a cell's metabolic pathways or processes change can have direct implications on whether the cell is cancerous. (RX3869 (Cote Expert Report) ¶ 54.)

Response to Finding No. 120

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because it does not explain for what purpose metabolomic biomarkers are purportedly "presently used."

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

120.1 Metabolite biomarkers include lipids, carbohydrates, nucleotides, and many other low-molecular-weight chemicals, and can be detected in tissue biopsy samples, body fluids, and even in breath through detection of cancer volatile organic compounds ("VOC") markers. (Cance (ACS) Tr. 609–10, 612–13; PX7131 (Cote Dep. at 112); RX3869 (Cote Expert Report) ¶ 54.)

Response to Finding No. 120.1

Complaint Counsel objects to the proposed finding because it is misleading and

improperly cites expert testimony.

The proposed finding is misleading to the extent it suggests that these purported metabolite biomarker molecules may be used for MCED testing.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

e. Exosome Biomarkers

121. Exosomes are best defined as small (40–100 nm) extracellular vesicles that are released from cells, whose membranes (walls) are composed of the plasma membrane of the cell and contain a variety of cellular components, including DNA, RNA, proteins and metabolites. (RX3184 (Edgar 2016) at 1)

Response to Finding No. 121

Complaint Counsel has no specific response to this proposed finding.

121.1 Because they are abundant, found in virtually all body fluids (including blood) and are representative of the cells from which they are derived, there is increasing interest by the academic and commercial communities in using exosomes as cancer biomarkers. (RX3745 (Wong, et al., 2019) at 2, 5; PX7131 (Cote Dep. at 111–12); RX3869 (Cote Expert Report) ¶ 56.)

Response to Finding No. 121.1

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because it does not define or explain what is meant by "using exosomes as cancer biomarkers."

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should

disregard this evidence and the proposed finding.

B. Clinical Oncology Tests and Testing Modalities

122. While there are many technologies that may be used for early cancer screening, only a few of them are currently in use in commercial tests today. (Cote Tr. 3728–30, 3736–37; RX3869 (Cote Expert Report) ¶ 57.)

Response to Finding No. 122

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because it does not identify any of the purported "many technologies" referenced. The proposed finding neither identifies those "technologies that may be used for early cancer screening," nor does it identify which "are currently in use in commercial tests today."

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

1. Types of Clinical Oncology Tests

123. Cancer screening and other tests using blood samples are referred to as "liquid biopsy" tests, even though tests of other body fluids (*e.g.*, urine) can sometimes also be referred to as liquid biopsy. [redacted]; Cance (ACS) Tr. 608–09; [redacted]; RX3869 (Cote Expert Report) ¶ 59.)

Response to Finding No. 123

[redacted]

[redacted]

124. Because of the minimal invasiveness and ease of use of liquid biopsy from a small sample of blood, blood-based clinical oncology tests have become a standard and essential part of oncology management, and there is enormous interest in developing blood-based cancer screening tests. [redacted]; Cance (ACS) Tr. 608–09; [redacted]; RX3869 (Cote Expert Report) ¶ 59.)

Response to Finding No. 124

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

125. Based on intended use and target patient populations, multiple types of clinical oncology tests have been developed to aid in the management of cancer at different stages of the "cancer continuum," including: (1) early cancer screening tests; (2) diagnostic aid to cancer tests; (3) therapy selection tests; (4) treatment response or acquired resistance monitoring tests; (5) minimal residual disease ("MRD") tests; and (6) hereditary risk assessment tests. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 60.)

Response to Finding No. 125

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because "cancer continuum" is undefined.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

a. Early cancer screening tests

126. Early cancer screening tests are used in asymptomatic individuals to detect cancer at the earliest, most treatable stage. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 61.) There are several types of tests for detecting single types of cancer at early stage, including imaging (mammography for breast and CT for high risk lung cancer screening), blood (PSA for prostate), or stool (colorectal cancer). (Cance (ACS) Tr. 606–07, 622–23; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 61.)

Response to Finding No. 126

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because it does not define "the earliest, most treatable stage."

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

127. Work on the development of cancer screening tests has primarily focused on the interrogation of DNA, RNA, proteins, metabolites or exosomes. (Cance (ACS) Tr. 609–10; RX3869 (Cote Expert Report) ¶ 61.)

Response to Finding No. 127

Complaint Counsel objects to the proposed finding because it is vague, misleading, unsupported, and improperly cites expert testimony.

The proposed finding is vague because "work," "development," and "metabolites" are undefined and unspecified. Further, the subjective qualification "primarily focused" is unsupported.

The proposed finding is misleading to the extent it suggests that MCED tests are being developed that rely solely on proteins, other metabolites, or exosomes.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—the entire paragraph is adapted nearly verbatim from Dr. Cote's report and represents only his opinion rather than market realities. Therefore, this Court should disregard the proposed finding.

128. Because blood-based cancer screening tests are designed to detect cancer at early stages, they must be very sensitive in order to detect the small amounts of analytes that small tumors release, though there are potential tradeoffs between sensitivity and specificity in early cancer screening, as well as the importance of detecting the cancer signal of origin. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 61.)

Response to Finding No. 128

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony.

The proposed finding is confusing because "as well as the importance of detecting the cancer signal of origin" does not seem to follow the rest of the sentence.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

b. Diagnostic aid to cancer ("DAC") tests

129. Once a cancer is suspected or has been detected, it is sometimes difficult to confirm the cancer and determine the type of cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 62.)

Response to Finding No. 129

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because "sometimes" is unspecified and it does not explain how the cancer has purportedly been detected. It is also unclear what particular testing or diagnostic context the proposed finding is referring to.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

130. DAC tests are used to help confirm the presence of cancer or to better specify the type of cancer in an individual who has cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 62.)

Response to Finding No. 130

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because it is unclear what "to better specify the type of cancer" means.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

c. Therapy selection tests

131. Therapy selection tests examine biomarkers (*e.g.*, known types of somatic mutations, hormone receptor status, oncogene protein expression) in individuals who have

already been diagnosed with cancer to help select the particular anti-cancer therapies to which the patient is most likely to respond. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.)

Response to Finding No. 131

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because it is not clear what "known types of somatic mutations" refers to.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

132. Because a patient's cancer has already been diagnosed via tissue biopsy or excision at this stage, therapy selection tests are more likely to rely on tissue biopsy samples as there is a much higher amount of cancer cells and other cancer biomarkers in the cancer tissue than are circulating in the body and available for testing. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.)

Response to Finding No. 132

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because "at this stage" is unspecified and "more likely" is unqualified. It is also unclear what context this refers to or why purportedly "a patient's cancer has already been diagnosed" at this stage.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

133. However, there is growing use of blood-based testing for cancer biomarkers to help select therapy in patients diagnosed with cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.) Particularly in the case of tissue-based cancer biomarker analysis, lower sensitivity testing methods may be used for therapy selection tests than for early cancer screening or diagnostic aid to cancer tests. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.)

Response to Finding No. 133

Complaint Counsel objects to the proposed finding because it is vague and improperly cites expert testimony.

The proposed finding is vague because though the finding begins by stating "however," the purported alternative is never specified or explained. It is also vague because it does not explain what "growing use" or "the case of tissue-based cancer biomarker analysis" means.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

d. Treatment response or acquired resistance monitoring tests

134. Treatment response or acquired resistance monitoring tests test cancer patients while treatment is ongoing to determine whether the patient has responded to or has acquired resistance to the treatment. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 64.)

Response to Finding No. 134

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

135. These tests can include imaging, and increasingly liquid biopsy tests for proteins or circulating tumor cells ("CTC"). (RX3869 (Cote Expert Report) ¶ 64.)

Response to Finding No. 135

Complaint Counsel objects to the proposed finding because it is vague, misleading, and improperly cites expert testimony.

The proposed finding is vague because "these tests" is undefined and unspecified. The proposed finding is misleading to the extent it suggests that MCED tests can rely on detecting circulating tumor cells.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

e. Minimal residual disease ("MRD") tests

136. MRD tests are used to determine whether a patient's cancer has recurred after successful treatment for cancer, *i.e.*, when a patient is in remission without symptoms or signs of disease and only a minimal amount of cancer cells and other cancer biomarkers are circulating in the body available to be tested at this stage. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 65).

Response to Finding No. 136

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

137. There are two types of MRD tests, those that are "tumor-informed" and those that are "tumor-naïve": tumor-informed MRD tests may use information about a patient's cancer, *i.e.*, the specific mutations/modifications that were present in the patient's original tumor biopsy, while tumor-naïve MRD tests are capable of detecting the recurrence of cancer without information about a given patient's cancer. (RX3869 (Cote Expert Report) ¶ 65.)

Response to Finding No. 137

Complaint Counsel objects to the proposed finding because it is vague and it improperly cites expert testimony.

The proposed finding is vague in that it states tumor-informed MRD tests "may" use information about a patient's cancer, and it does not define or explain what "information about a patient's cancer" references.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

f. Hereditary risk assessment tests

138. Hereditary risk assessment tests examine healthy individuals' germline (*i.e.*, inherited) mutations/variants in cancer susceptibility genes to assess risks of hereditary cancer, based on personal and family history. (Cote Tr. 3734; RX3869 (Cote Expert Report) ¶ 66.) These tests do not test any cancer that has actually developed in the individual being tested. (Cote Tr. 3734; RX3869 (Cote Expert Report) ¶ 66.)

Response to Finding No. 138

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

139. Because hereditary risk assessment tests are based on DNA collected from any tissue (for example, a mouth swab) or from saliva or blood, they do not have the sensitivity required for early cancer screening. (RX3869 (Cote Expert Report) ¶ 66.)

Response to Finding No. 139

Complaint Counsel objects to the proposed finding because it is confusing and

improperly cites expert testimony.

The proposed finding is confusing in that it says hereditary risk assessment tests "do not have the sensitivity required" for early cancer screening tests; but, as their name implies, hereditary risk assessment tests are not designed to screen for the presence of cancer. Moreover, the fact that the DNA is collected from a mouth swab, saliva, or blood is not the reason these tests may lack the sensitivity to detect the presence of cancer, as the proposed finding implies.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

2. The State of Early Cancer Screening Tests Today

140. The most pressing unmet need in cancer early detection is to identify cancers for which there are no existing recommended screening tests. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3308–09; Aravanis (Illumina) Tr. 1937.)

Response to Finding No. 140

Complaint Counsel objects to the proposed finding because it is inherently speculative. For support, Respondents cite only to a GRAIL company filing that provides no source or basis for this claim and the unfounded, self-serving testimony of Grail and Illumina executives. This evidence is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this evidence as well as lack of foundation or explanation for the executives' base conjecture, this proposed finding of fact should be disregarded.

141. There are no standard of care screening tests for most types of cancer, including some of the major causes of cancer mortality, such as cancers of the pancreas, ovary, stomach, bone marrow, lymph nodes, etc. [redacted]; Cote Tr. 3728–30; RX3869 (Cote Expert Report) ¶ 69.)

Response to Finding No. 141

142. In most of these cases, the cancers are not diagnosed before a patient exhibits symptoms, which generally will not occur until the cancer has progressed to a late and often incurable stage. ; RX3869 (Cote Expert Report) ¶ 69.)

Response to Finding No. 142

143. The United States Preventive Services Task Force ("USPSTF") is an independent panel of experts that makes recommendations about clinical preventive services (such as cancer screening) which influence the coverage and adoption of medical services. (*See* RX3867 (Expert Report) ¶ 39.)

Response to Finding No. 143

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Deverka in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

144. USPSTF recommends screening for four cancer types: breast, cervical, lung and colorectal. (RX3723 (USPSTF) at 2–3, 7; Cote Tr. 3728–29.)

Response to Finding No. 144

Complaint Counsel has no specific response to this proposed finding.

145. Other organizations, such as the American Cancer Society, also recommend screening for prostate cancer. (Cance (ACS) Tr. 606; Cote Tr. 3730; RX3869 (Cote Expert Report) ¶ 67.) Below is an overview of the cancer screening tests that are recommended as the "standard of care":

Response to Finding No. 145

The final sentence of the proposed finding is vague and unsupported, because "standard of care" is not defined and no evidence is provided. Therefore, this Court should disregard the proposed finding.

145.1 Breast Cancer. USPSTF recommends biennial screening via mammography for women ages 50 to 74. (RX3723 (USPSTF, A and B Recommendations) at 2; Cance (ACS) Tr. 606; Cote Tr. 3729–30).

Response to Finding No. 145.1

Complaint Counsel has no specific response to this proposed finding.

145.1.1 A mammogram is an X-ray of the breast, which has the associated risk of having repeated exposure to a small amount of radiation. (RX3104 (CDC).)

Response to Finding No. 145.1.1

Complaint Counsel has no specific response to this proposed finding.

145.1.2 When suspicious results are obtained, the patients will undergo either a needle biopsy or fine needle aspiration ("FNA"), or a more extensive removal of tissue, to rule out a diagnosis of cancer. (RX3869 (Cote Expert Report) ¶ 67.)

Response to Finding No. 145.1.2

This proposed finding is vague and improper expert testimony. It is vague because "suspicious results" is not defined. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence regarding various organizations' recommended screening guidelines, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

145.2 Cervical Cancer. For women ages 21 to 29, USPSTF recommends screening every 3 years with cervical cytology (*i.e.*, a pap test) alone; for women ages 30 to 65, every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting). (RX3723 (USPSTF, A and B Recommendations) at 3; Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

Response to Finding No. 145.2

Complaint Counsel has no specific response to this proposed finding.

145.2.1 Both pap tests and hrHPV testing are invasive procedures which include gynecological examination of the vagina and the cervix, and collection of cells and mucus from the cervix and the area around it, while samples for hrHPV testing are subsequently analyzed using PCR. (RX3106 (CDC, What Should I Know About Screening?) at 1; Cance (ACS) Tr. 606; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 67.)

Response to Finding No. 145.2.1

This proposed finding is improper expert testimony. Specifically, the only source cited that references PCR analysis is Dr. Cote's report. In fact, this entire "finding" is copied and pasted verbatim from Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See*

Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

145.3 Colorectal Cancer. USPSTF recommends screening for colorectal cancer in all adults aged 50 to 75 years. (RX3723 (USPSTF, A and B Recommendations) at 3; Cance (ACS) Tr. 606; Cote Tr. 3729–30).

Response to Finding No. 145.3

Complaint Counsel has no specific response to this proposed finding.

145.3.1 Recommended stool-based tests include the high-sensitivity guaiac fecal occult blood test ("gFOBT"), fecal immunochemical test ("FIT"), and stool DNA test ("sDNA-FIT"). (RX3730 (USPSTF, Screening for Colorectal Cancer) at 2–3.) Recommended direct visualization tests to screen for colorectal cancer include colonoscopy, CT colonography, and flexible sigmoidoscopy. (RX3730 (USPSTF, Screening for Colorectal Cancer) at 3.)

Response to Finding No. 145.3.1

Complaint Counsel has no specific response to this proposed finding.

145.3.2 Colonoscopy is the gold standard for colorectal cancer screening and need only be done every ten years, but it is invasive and requires bowel preparation, anesthesia or sedation. (Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

Response to Finding No. 145.3.2

Complaint Counsel does not disagree that Dr. Cance testified that colonoscopy is the "gold standard" for colorectal cancer. (Cance (ACS) Tr. 606). However, the rest of this finding is unsupported and improper expert testimony. It is unsupported because the evidence cited does not mention these details about colonoscopy. Further, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence.

145.4 Lung Cancer. Lung cancer represents the most common killer among cancers, but USPSTF recommendations for lung cancer screening are limited to the high-

risk smoking population—adults aged 50 to 80 years who have a 20 pack-a-year smoking history and currently smoke or have quit within the past 15 years. (PX0043 (GRAIL) at 97, 110; *see also* Bishop (GRAIL) Tr. 1392[redacted] RX3723 (USPSTF, A and B Recommendations) at 7; Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

Response to Finding No. 145.4

Complaint Counsel has no specific response to this proposed finding.

145.4.1 This high-risk population accounts for only 33% of all lung cancers, meaning there is no effective screening in place for the vast majority of lung cancer diagnoses. (PX0043 (GRAIL) at 97, 110; *see also* Bishop (GRAIL) Tr. 1392; [redacted]

Response to Finding No. 145.4.1

Complaint Counsel has no specific response to this proposed finding.

145.4.2 USPSTF recommends annual screening for lung cancer with low-dose computed tomography ("LDCT"), which carries non-negligible radiation risk and is expensive. (RX3723 (USPSTF, A and B Recommendations) at 7; RX3107 (CDC, Who Should Be Screened for Lung Cancer?); RX3869 (Cote Expert Report) ¶ 67.)

Response to Finding No. 145.4.2

This proposed finding is vague and improper expert testimony. It is vague because the terms "non-negligible" and "expensive" are not defined. Further, this qualitative statement that LDCT "carries non-negligible radiation risk and is expensive" is not supported by the cited evidence, except for Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

145.5 Prostate Cancer. Although not listed by the USPSTF, screening for prostate cancer involves a serum test (most commonly) for serum PSA, digital rectal examination ("DRE"), and when suspicious results are obtained, "sextant" prostate needle biopsies (6 biopsies per side, 12 or more total biopsies) that are now often done under radiographic guidance to determine the most suspicious areas. (RX3034 (American

Cancer Society, Recommendations for Prostate Cancer Early Detection) at 1; Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

Response to Finding No. 145.5

The proposed finding is vague, misleading, and unsupported. It is vague because the term "suspicious" is not defined. It is misleading because this "finding" is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report ¶ 67), even though Respondents do not attribute it to him. This finding is not actually supported by the evidence it does cite, leaving it unsupported. Therefore, this Court should disregard the proposed finding.

145.5.1 A problem with the PSA test is that many factors can affect PSA levels, including non-malignant conditions that affect the prostate, while DRE is uncomfortable, invasive and lacks specificity for cancer. (RX3105 (CDC, What Is Screening for Prostate Cancer?) at 1–2; RX3869 (Cote Expert Report) ¶ 67.)

Response to Finding No. 145.5.1

The proposed finding is vague, misleading, and improper expert testimony. It is vague because "many factors" and "uncomfortable" are not defined. It is misleading because this "finding" is copied and pasted verbatim from Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

146. Standard, recommended screening tests nearly all come with major issues in their use, interpretation and follow-up. (Cote Tr. 3813–14; RX3869 (Cote Expert Report) ¶ 68.) The standard of care cancer screening tests and their follow-up to rule out a cancer diagnosis (generally, a surgical procedure) currently recommended by the USPSTF are either invasive, burdensome, or carries potential risks to patients, creating a need for blood-based single cancer screening tests. [redacted]; Cote Tr. 3813–14; RX3869 (Cote Expert Report) ¶ 68.)

Response to Finding No. 146

[redacted]

[redacted]

147. Importantly, nearly all recommended screening tests are often "positive"—that is, signal the possible presence of cancer, in many more cases compared to the times they actually detect cancer, which affects what is known as the "Positive Predictive Value" of such tests. (RX3869 (Cote Expert Report) ¶ 68 *see infra* PFF ¶ 174.)

Response to Finding No. 147

This proposed finding is misleading and improper expert testimony. It is misleading because it is copied and pasted verbatim from Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

3. **Modalities Used for Cancer Screening**

148. Several types of technologies are being used for screening tests today or are being studied for screening tests in development. (PX7095 (Hill (Emory) Dep. at 27–28); [redacted]; Cance (ACS) Tr. 612–13.) Scientists and doctors recognize today that it is impossible to speculate which modality for cancer screening will be the most successful. [redacted]; Cance (ACS) Tr. 620; PX7086 (Cance (ACS) Dep. at 102); RX3869 (Cote Expert Report) ¶ 70.)

Response to Finding No. 148

[redacted]

[redacted]

a. Imaging

149. For over half a century, imaging technologies have been the standard of care for early-stage cancer detection and screening in the United States. (RX3869 (Cote Expert Report) ¶ 71.) Over the years, imaging technologies progressed from standard x-rays for mammography and lung to low-energy X-rays, 3–D mammography, ultrasound, MRI (Magnetic Resonance Imaging), CT (Computed Tomography), and PET-CT (Positron Emission Tomography), etc. (RX3869 (Cote Expert Report) ¶ 71.)

Response to Finding No. 149

Complaint Counsel objects to the proposed finding because it is misleading, it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading to the extent it suggests that MCED testing is feasible using imaging technologies alone.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only

his opinion rather than market realities. [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and disregard the proposed finding.

150. Imaging technologies provide direct or indirect views of structures inside the body, which allow doctors to detect, locate and stage a tumor. (RX3869 (Cote Expert Report) ¶ 71.) Imaging technologies thus may be used for cancer screening, diagnosis, and monitoring. (RX3869 (Cote Expert Report) ¶ 71.) Imaging technologies are currently the most commonly used and commercially available technique for cancer screening. (RX3869 (Cote Expert Report) ¶ 71.)

Response to Finding No. 150

This proposed finding is misleading and improper expert testimony. It is misleading because it is copied and pasted verbatim from Dr. Cote's report, and no further evidence is cited. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

150.1 For example, both the National Cancer Institute and the American Cancer Society recommend mammograms or MRIs along with mammograms for breast cancer screening, and a low-dose CT scan for lung cancer screening. (RX3502 (National Cancer Institute, Screening Tests) at 2; RX3029 (American Cancer Society, Guidelines for the Early Detection of Cancer) at 1, 3; Cance (ACS) Tr. 606; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 71.)

Response to Finding No. 150.1

This proposed finding is confusing, misleading, and improper expert testimony. It is confusing because it begins "[f]or example," without providing any context or explanation for how it serves as an example. It is misleading because it is copied and pasted verbatim from Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

151. Although traditional imaging screenings are typically focused on screening for cancer in a single organ of the body, PET, CT, and PET-CT may in some circumstances be used for whole-body scanning, with PET-CT being more accurate in detecting cancer and providing fewer equivocal findings than PET alone, CT alone, or separately acquired PET and CT studies in a head-to-head comparison. (RX3624 (Schöder & Gonen 2007) at 9.)

Response to Finding No. 151

Complaint Counsel has no specific response to this proposed finding.

152. However, PET-CT scan is not recommended for routine early cancer screening, because of cost and radiation concerns, as well as the inability of PET-CT scanning to detect very small tumors. (RX3624 (Schöder & Gonen 2007) at 9–10; Cote Tr. 3812–13; RX3869 (Cote Expert Report) ¶ 72.)

Response to Finding No. 152

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague in its use of "not recommended" as it is unclear to whom this is attributed and whether they are merely silent or affirmatively recommend against.

The proposed finding is misleading to the extent it suggests that liquid biopsy *followed by* positive reflex PET-CT scan for cancer localization may not prove an optimal method for MCED

testing. [redacted] The Schöder et al. review paper cited is inapposite because it was assessing whether PET-CT is practical to use as a standalone first-line method of early cancer screening, not as a reflex test given only to patients who first show a positive liquid biopsy. (RX3624 (Schöder & Gonen, 2007) at 1).

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 152.1 Diagnostic PET-CT will necessitate further evaluation of true-positive or false-positive finding and therefore impose downstream costs on the health care system as a whole. (RX3624 (Schöder & Gonen 2007) at 9–10.)

Response to Finding No. 152.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence.

The proposed finding is vague regarding what is the purpose for or context in which

Diagnostic PET-CT is being employed.

The proposed finding is misleading to the extent it suggests that liquid biopsy *followed by* positive reflex PET-CT scan for cancer localization may not prove an optimal method for MCED testing. [redacted] The Schöder review paper cited is inapposite because it was assessing whether PET-CT is practical to use as a standalone first-line method of early cancer screening, not as a reflex test given only to patients who first show a positive liquid biopsy. (RX3624 (Schöder & Gonen, 2007) at 1). Therefore, this Court should disregard the proposed finding.

152.2 A diagnostic PET-CT exposes an individual to 62 times more radiation than a mammogram and 12 times more than a low-dose computed tomography (LDCT), which is only approved in high-risk smokers. (RX0661 (GRAIL) at 36.)

Response to Finding No. 152.2

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence.

The proposed finding is vague regarding what is the purpose for or context in which Diagnostic PET-CT is being employed.

The proposed finding is misleading to the extent it suggests that liquid biopsy *followed by* positive reflex PET-CT scan for cancer localization may not prove an optimal method for MCED testing. [redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

153. The cost (or reimbursement) for imaging-based cancer screening is relatively low. (RX3869 (Cote Expert Report) ¶ 73.) The national average total reimbursement for breast cancer screening is only about $353 per person screened, taking into consideration follow-up ultrasonography, biopsy and MRI costs. (RX3414 (Kunst et al., 2020) at 2.)

Response to Finding No. 153

The proposed finding is vague, misleading, and improper expert testimony. It is vague because Respondents do not define "relatively low." It is misleading because it is copied and pasted verbatim from Dr. Cote's report, and the first sentence specifically has no evidence cited besides Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

154. Similarly, the average annual reimbursement of low-dose CT scan for lung cancer screening under Medicare is about $241 per person screened. (RX3593 (Pyenson et al., 2014) at 2; RX3869 (Cote Expert Report) ¶ 73.)

Response to Finding No. 154

Complaint Counsel has no specific response to this proposed finding.

b. Proteomics

155. Protein biomarkers have also been used for many years for early stage cancer detection and screening. (Cance (ACS) Tr. 606; Cote Tr. 3730; RX3869 (Cote Expert Report) ¶ 74.)

Response to Finding No. 155

This proposed finding is vague, misleading, against the weight of the evidence, unsupported, and improper expert opinion.

It is vague because Respondents do not define "many years."

The proposed finding is misleading to the extent it suggests that proteomics is used to test for more than one type of cancer within a single test, which is not the case and not supported by any of the cited sources.

[redacted]

It is unsupported because the cited testimony from Dr. Cance is completely unrelated to this claim.

Instead, the only cited evidence is Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only

source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 155.1 Protein biomarkers are commonly analyzed using antibodies that specifically bind to the protein and covalently link with certain modifiers for easy detection. (RX3869 (Cote Expert Report) ¶ 74.)

Response to Finding No. 155.1

This proposed finding is vague, unsupported, and improper expert testimony. It is vague because Respondents do not explain what is meant by "commonly analyzed." It is unsupported because the only evidence cited is Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 155.2 For example, enzyme or fluorescent dye-linked antibodies specific to cancer biomarkers are also used to detect the presence of such antigens in bodily fluids in technologies called ELISA (enzyme-linked immunosorbent assay) and immunochemistry ("IC"), which are used for both cancer diagnosis and screening. (Cote Tr. 3736–37, 3872; RX3869 (Cote Expert Report) ¶ 74.)

Response to Finding No. 155.2

This proposed finding is misleading and improper expert testimony. It is misleading because it is copied and pasted verbatim from Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

156. Proteomics is currently used in a variety of early screening tests for several cancers. (Cance (ACS) Tr. 606; Cote Tr. 3729–30, 3736–37, 3872; RX3869 (Cote Expert Report) ¶ 75.)

Response to Finding No. 156

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading because it suggests that proteomics is used to test for more than one type of cancer within a single test, which is not the case and not supported by any of the cited sources.

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court

should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

156.1 For example, a blood-based ELISA test for the level of PSA has been recommended by both the National Cancer Institute and the American Cancer Society for early stage screening of prostate cancer. (RX3502 (National Cancer Institute); RX3029 (ACS) at 4; Cance (ACS) Tr. 606; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 75.)

Response to Finding No. 156.1

This proposed finding is confusing, unsupported, and improper expert opinion. It is confusing because it begins "[f]or example," without providing any context or explanation for how it serves as an example. It is unsupported because none of the cited evidence supports this claim. In fact, the cited evidence suggests the opposite. The National Cancer Institute website states that "expert groups no longer recommend routine PSA testing for most men." (RX3502 at 3 (National Cancer Institute, Screening Tests)). The American Cancer Society website states that "[r]esearch has not yet proven that the potential benefits of testing [for prostate cancer] outweigh the harms of testing and treatment. We believe that men should not be tested without first learning about what we know and don't know about the risks and possible benefits of testing and treatment." (RX3029 at 3 (American Cancer Society, Guidelines for the Early Detection of Cancer)). The cited testimony from Dr. Cance does not support this statement either.

The only remaining evidence that Respondents rely on for this statement is Dr. Cote's testimony and report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

157. The costs for proteomics tests are fairly low. (RX3869 (Cote Expert Report) ¶ 76.) Quest Diagnostics offers the PSA prostate cancer screening test for $75, while, according to the 2021 Fee Schedule, the Centers for Medicare & Medicaid Services ("CMS") reimburses PSA prostate cancer screening for $19.31. (RX3595 (QuestDirect) at 1; RX3869 (Cote Expert Report) ¶ 76.)

Response to Finding No. 157

The proposed finding is vague, misleading, and improper expert testimony. It is vague because Respondents do not define "fairly low." It is misleading because it is copied and pasted verbatim from Dr. Cote's report. The first sentence specifically has no evidence cited besides Dr. Cote's report. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

c. Polymerase Chain Reaction

158. Polymerase Chain Reaction ("PCR") is a DNA amplification method that can be used for many different types of applications, including to detect specific genomic mutations or methylation biomarkers known to be associated with cancer. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 77.)

Response to Finding No. 158

The proposed finding is vague, misleading, and against the weight of the evidence, and it improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the term "DNA amplification method" is undefined.

The proposed finding is misleading to the extent it suggests that PCR-based detection platforms can be used for MCED testing. [redacted]

The proposed finding is improper because this Court held that experts shall not be cited

to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 77). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 77). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 158.1 Using PCR, copies of very small amounts of DNA sequences are exponentially amplified in a series of temperature changes. (RX3869 (Cote Expert Report) ¶ 77.) PCR tests can be used to evaluate all types of samples, including cancer biopsy tissue, urine, stool, saliva or blood plasma. (RX3869 (Cote Expert Report) ¶ 77).

Response to Finding No. 158.1

The proposed finding is vague and improperly cites expert testimony. Dr. Cote is not

qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the terms "small amounts," "exponentially," and "temperature changes" are ambiguous.

The proposed finding is also vague because "very small amounts of DNA sequences are exponentially amplified in a series of temperature changes" is an incomplete description of PCR. PCR involves successive cycles of temperature changes, during which the DNA template molecule is denatured into single strands, short DNA primers anneal to the template flanking the region to amplified, and a DNA polymerase enzyme extends the primers into new complementary strands. (CCFF ¶ 1441.)

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 77). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 77). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 158.2 PCR can use either DNA, such as cell-free DNA present in the blood plasma, or, through a reverse transcription process that first reverse-transcribes RNA into complementary DNA ("cDNA"), use RNA as templates for the genomic amplification in RT-PCR (real time-PCR). (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 77.)

Response to Finding No. 158.2

The proposed finding is vague and improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because it conflates reverse transcription PCR (typically abbreviated as "RT-PCR") and real time PCR, also known as quantitative PCR (typically abbreviated as "qPCR").

The proposed finding is confusing and nonsensical because it states "PCR can … use RNA as templates for the genomic amplification." It is unclear what "the genomic amplification" refers to, but it makes no sense, as RNA does not represent a genomic template (save for the genome of an RNA virus, which is unlikely to be what Respondents are referring to as they struggle to make an apparently elusive point).

The proposed finding is also vague because the terms "reverse transcription process" and "complementary DNA" are undefined.

The proposed finding is improper because this Court held that experts shall not be cited

to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 77). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 77). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

158.3 PCR is highly sensitive and requires only minimal amount of sample for detection and amplification of specific sequences. (RX3869 (Cote Expert Report) ¶ 77.)

Response to Finding No. 158.3

The proposed finding is vague, misleading, and it improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr.

Cote is not reliable.

The proposed finding is vague because the terms "highly sensitive" and "minimal amount" are ambiguous. It is also vague because it does not provide any context or details about the application(s) it is referring to.

The proposed finding is misleading to the extent it suggests that PCR-based detection platforms can be used for MCED testing. [redacted] The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 77). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 77). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition,

Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

159. Since its invention in 1983, many improved PCR techniques have been developed and used in clinical cancer testing. (RX3869 (Cote Expert Report) ¶ 78.) Multiplex PCR allows simultaneous detection of multiple targets in a single test, with a different pair of primers for each target. (RX3686 (Thermo Fisher) at 1–2; RX3869 (Cote Expert Report) ¶ 78.)

Response to Finding No. 159

The proposed finding because it is misleading and improper. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

Respondents' citation to RX3686 is misleading to the extent that it suggests the Thermo Fisher Ion AmpliSeq Exome RDY Kit is an example of the use of a PCR-based *detection* platform such as qPCR or dPCR as one of the "modalities used for cancer screening" (i.e., the title of this section of Respondents' findings) ((*see* Response to RPFF ¶ 159.2, below (examining Dr. Cote's misunderstanding of PCR and NGS technology).

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the first sentence of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 78). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard the first sentence of Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

159.1 Multiplex PCR can generate higher throughput than traditional (single-plex) PCR and obtains more information with less sample. (RX3686 (Thermo Fisher) at 1–2; RX3869 (Cote Expert Report) ¶ 78.)

Response to Finding No. 159.1

The proposed finding because it is vague and misleading. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the term "traditional (single-plex) PCR" is undefined, and the terms "higher throughput," "more information," and "less sample" are ambiguous.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 78). [redacted]

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 159.2 For example, Thermo Fisher's Ion AmpliSeq Exome RDY Kit enables ultrahigh-multiplex PCR exome enrichment of approximately 294,000 primer pairs across 12 primer pools, or about 24,500 primer pairs in each PCR pool, showing the ultrahigh capability of the new PCR technology. (RX3686 (Thermo Fisher) at 2; RX3869 (Cote Expert Report) ¶ 78.)

Response to Finding No. 159.2

Complaint Counsel objects to the proposed finding because it is misleading, incorrect, and against the weight of the evidence, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading and incorrect because it suggests that the Thermo Fisher Ion AmpliSeq Exome RDY Kit is an example of the use of a PCR-based *detection* platform such as qPCR or dPCR as one of the "modalities used for cancer screening" (i.e., the title of this section of Respondents' findings). Respondents and Dr. Cote (on whom they rely for this finding) must not understand the difference between (i) PCR-based *detection* platforms such as qPCR or dPCR and (ii) PCR *amplification* utilized as one step within the NGS library preparation process. The Thermo Fisher Ion AmpliSeq product is an example of the latter. Thermo Fisher's Ion AmpliSeq kits are used in the library preparation step of the overall NGS

workflow, hence the "Seq" incorporated into the product name. (RX3686 (Thermo Fisher) at 1 ("[T]he Ion AmpliSeq Exome RDY Kit allows rapid *sequencing* of key exonic regions of the genome[.]"). Respondents appeared to be attempting in this section of their findings to show the Court which detection platforms *other than NGS* are purportedly suitable for cancer screening. Yet as evidence they point to an NGS-related product. This Court should reject this misguided proposed finding. Moreover, this egregious mistake is another example demonstrating Dr. Cote has no expertise in NGS technology and fundamentally misunderstands the products.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not

accord Dr. Cote's opinion any weight and should disregard the proposed finding.

160. Another category of new PCR technology is digital PCR (dPCR). (Cote Tr. 3872; RX3869 (Cote Expert Report) ¶ 79.)

Response to Finding No. 160

The proposed finding is vague and improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the term "digital PCR (dPCR)" is undefined. It is also vague because it does not explain what "new" means in this context.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 79). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 79). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition,

Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 160.1 For example, Thermo Fisher's microfluidic digital PCR OpenArray system uses a microscope slide-sized plate with 3,072 through-holes, on a system that can run up to four OpenArray plates simultaneously, allowing for generation of over 12,000 data points in a single run. (RX3692 (Thermo Fisher).)

Response to Finding No. 160.1

The proposed finding is vague, misleading, and against the weight of the evidence. Additionally, Respondents' citation to RX3692 is in contravention of this Court's order that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3692 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. Thus, the Court should disregard this proposed evidence.

The proposed finding is vague because the terms "microfluidic digital PCR OpenArray system" and "through-holes" are undefined, and the opening phrase "for example" is provided without context.

The proposed finding is misleading to the extent it suggests that PCR-based detection platforms can be used for MCED testing. [redacted] The proposed finding is also

misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 79). [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 160.2 Combinati is developing an Absolute Q Microfluidic Array Partitioning (MAP) dPCR system with 20,000 microchambers, pushing the microfluidic digital PCR technology forward even further. (RX3147 (Combinati) at 3; RX3869 (Cote Expert Report) ¶ 79.)

Response to Finding No. 160.2

The proposed finding misattributes the source of a document and, vague, and misleading. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

Complaint Counsel objects to the attribution of RX3147 (which Respondents appear to have captured from Combinati's website) to Combinati as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. No discovery was

taken in this matter from Combinati, and the document was not produced by Combinati. The document constitutes hearsay. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is vague because the terms "Microfluidic Array Partitioning (MAP) dPCR system," "microchambers," and "microfluidic digital PCR technology" are undefined. It is also vague as to what "pushing the microfluidic digital PCR technology forward even further" means.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities (RX3869 (Cote Report) ¶ 79). [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

161. Because of its high sensitivity, PCR is currently used in a variety of early screening tests for several cancers. (Cote Tr. 3736–3737; RX3869 (Cote Expert Report) ¶ 80.) For example, both the National Cancer Institute and the American Cancer Society recommend a stool-based PCR test for early stage screening of colorectal cancer and human papillomavirus ("HPV") PCR test for early stage screening of cervical cancer. (RX3502 (National Cancer Institute) at 2; RX3029 (ACS) at 1–2; RX3869 (Cote Expert Report) ¶ 80.)

Response to Finding No. 161

Complaint Counsel objects to the proposed finding because it misattributes the source of a document, it is misleading and unsupported, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not qualified.

Complaint Counsel objects to the attribution of RX3502 (which Respondents appear to have captured from the ACS website) to ACS as the source of the document (ACS did not produce the document), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document appears incomplete, and fails to include relevant related material that is linked from the captured pages. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading because it suggests that PCR is used to screen for multiple cancers in a single test, which is not supported by any of the sources cited.

The proposed finding is also misleading because it relates to tests for a single type of cancer, not the MCED testing at issue in this case.

The proposed finding is unsupported because the source cited (RX3502) does not indicate that the National Cancer Institute and the American Cancer Society recommend a stool-based "PCR test."

The proposed finding is also misleading because the HPV PCR test does not directly test for the presence of cancer as MCED tests do, but rather merely tests for the presence of human papillomavirus (RX3502 at 2)—an *infection* that is known to be *linked* to cervical cancer. This is simply not relevant to the highly sensitive NGS-based ctDNA assays employed for the MCED testing at issue in this case.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as a source of evidence supporting facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and disregard the proposed finding.

162. Many PCR-based cancer screening tests have low costs, though some are reimbursed at higher costs. (RX3869 (Cote Expert Report) ¶ 81.) For example, while the maximum cost of Cologuard could be $649, the CMS 2021 Fee Schedule for an HPV PCR test is only $35.09. (RX3306 (Healthline Media) at 2; RX3869 (Cote Expert Report) ¶ 81.)

Response to Finding No. 162

The proposed finding is misleading, against the weight of the evidence, and vague, and it improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading to the extent it suggests that PCR-based detection

platforms can be used for MCED testing. Cologuard is not an MCED test and not even a liquid biopsy test. [redacted]

The proposed finding is vague because "PCR-based cancer screening tests" is not defined, and it is thus not clear whether this refers to tests that purportedly use PCR-based *detection* platforms such as qPCR or dPCR or to tests that merely incorporate PCR amplification into the workflow but require a different detection technology.

The proposed finding is vague as it is not clear what it means that the maximum cost of Cologuard "could be" $649. It also does not identify the purported "many pcr-based cancer screening tests" referenced or the purported "some" PCR-based cancer screening tests referenced.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the first sentence of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 81). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. [redacted]

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

d. Microarrays

163. A microarray is an orderly arrangement of many individual fragments of probes, such as DNAs, RNAs, or proteins, attached to a solid support called chips. (RX3869 (Cote Expert Report) ¶ 82.)

Response to Finding No. 163

The proposed finding is vague, misleading, against the weight of the evidence, and it improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the term "probes" is undefined, and the term "many individual fragments" is ambiguous.

The proposed finding is misleading to the extent it suggests that microarray platforms can be used for MCED testing. [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents."

(Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 82). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 82). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 163.1 Microarray-based genomic tests may be used to detect the presence or absence of specific genomic mutations and/or methylations in a sample, because mutated and/or methylated DNA bind to the probes differently than normal DNA. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 82.)

Response to Finding No. 163.1

The proposed finding is vague, misleading, and against the weight of the evidence, and it improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because "bind to the probes differently" is undefined and not explained. It also does not explain what application it is referring to or what "sample" it is referring to.

The proposed finding is misleading to the extent it suggests that microarray platforms can be used for MCED testing. [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 82). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 82). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that

his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 163.2 Researchers, *e.g.*, the Cancer Genome Atlas and the Human Tumor Atlas Network, are continually generating data and improving algorithms to identify new associations that may be incorporated into microarray-based tests. (RX3869 (Cote Expert Report) ¶ 82.)

Response to Finding No. 163.2

The proposed finding is vague and improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the terms "new associations" and "may be incorporated" are vague. It also does not identify the purported "microarray-based tests" referenced.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his expert testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 82). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 82). Rather than citing directly to the Cancer Genome Atlas or the Human Tumor Atlas Network, Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard

Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

164. Microarrays provide a high-throughput platform for simultaneously screening tens of thousands of biomolecular interactions. (RX3869 (Cote Expert Report) ¶ 83; *see also* Cote Tr. 3736–37).

Response to Finding No. 164

The proposed finding is misleading, against the weight of the evidence, and vague, and it improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading to the extent that is suggests the throughput of microarray platforms is comparable to the high throughput of NGS platforms. Thermo Fisher's Felton explained that while microarray technology "can generate a large number of data points, their throughput is relatively low compared to the highest throughput gene sequencing platforms." (PX7097 (Felton (Thermo Fisher) Dep. at 41)).

The proposed finding is misleading to the extent it suggests that microarray platforms can be used for MCED testing. [redacted]

[redacted]

The proposed finding is vague because the term "biomolecular interactions" is ambiguous and undefined.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 83). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 83). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's

opinion any weight.

164.1 For example, Thermo Fisher's GeneChip Human Genome U133 Plus 2.0 Array allows for analysis of over 47,000 human genes and transcripts at one time. (RX3682 (Thermo Fisher) at 1; Cote Tr. 3876.)

Response to Finding No. 164.1

The proposed finding is misleading and against the weight of the evidence, and Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading to the extent that is suggests the throughput of microarray platforms is comparable to the high throughput of NGS platforms. Thermo Fisher's Felton explained that while microarray technology "can generate a large number of data points, their throughput is relatively low compared to the highest throughput gene sequencing platforms." (PX7097 (Felton (Thermo Fisher) Dep. at 41)).

The proposed finding is misleading to the extent it suggests that microarray platforms can be used for MCED testing. [redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 83). [redacted] In addition, Dr. Cote's opinion about

which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 164.2 Thermo Fisher's Genome-Wide Human SNP Array 6.0 chip features 1.8 million genetic markers for single nucleotide polymorphisms (SNPs) and copy number variations (CNVs). (RX3684 (Thermo Fisher) at 2.)

Response to Finding No. 164.2

The proposed finding is misleading and against the weight of the evidence. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading to the extent that is suggests the throughput of microarray platforms is comparable to the high throughput of NGS platforms. Thermo Fisher's Felton explained that while microarray technology "can generate a large number of data points, their throughput is relatively low compared to the highest throughput gene sequencing platforms." (PX7097 (Felton (Thermo Fisher) Dep. at 41)).

The proposed finding is misleading to the extent it suggests that microarray platforms can be used for MCED testing. [redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities (RX3869 (Cote Report) ¶ 83), even though Respondents do not cite Dr. Cote as the source. [redacted]

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

164.3 Agilent Technologies' SurePrint G3 Human Gene Expression Microarrays allow for analysis of over 56,600 genes and transcripts at one time. (RX3019 (Agilent Technologies).)

Response to Finding No. 164.3

The proposed finding misattributes the source of a document and is misleading. Additionally, Respondents' citation to RX3019 is in contravention of this Court's order that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3019 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. Thus, the Court should disregard this proposed evidence.

Complaint Counsel objects to the attribution of RX3019 (which Respondents appear to have captured from Agilent's website) to Agilent as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. No discovery was taken in this matter from Agilent, and the document was not produced by Agilent. The document constitutes

hearsay. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 83). [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

164.4 Agilent Technologies' Human Genome CGH Microarrays offers up to 1 million probes for genome-wide CNV identification and characterization. (RX3869 (Cote Expert Report) ¶ 83; RX3020 (Agilent Technologies).)

Response to Finding No. 164.4

The proposed finding is vague, it misattributes the source of a document, and it is misleading and against the weight of the evidence. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the terms "probes" and "CNV identification and characterization" are undefined.

Complaint Counsel objects to the attribution of RX3020 (which Respondents appear to

have captured from Agilent's website) to Agilent as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. No discovery was taken in this matter from Agilent, and the document was not produced by Agilent. The document constitutes hearsay. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading to the extent it suggests that microarray platforms can be used for MCED testing. [redacted]

Respondents' citation to RX3020 is misleading because RX3020 does not mention anything about "up to 1 million probes." Instead, Respondents rely on Dr. Cote's report, from which the entire proposed finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 83). Thus, the proposed finding represents only Dr. Cote's opinion rather than market realities. [redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

164.5 Agilent Technologies' Human DNA Methylation Microarrays use 60–oligomer probes for 28,500 CpG islands in human, representing 237,227 unique probes for DNA methylation. (RX3018 (Agilent Technologies) at 2; RX3869 (Cote Expert Report) ¶ 83.)

Response to Finding No. 164.5

The proposed finding is vague, it misattributes the source of a document, and it is misleading and against the weight of the evidence. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the terms "oligomer probes," "CpG islands," and "unique probes" are undefined.

Complaint Counsel objects to the attribution of RX3018 (which Respondents appear to have captured from Agilent's website) to Agilent as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. No discovery was taken in this matter from Agilent, and the document was not produced by Agilent. The document constitutes hearsay. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading to the extent it suggests that microarray platforms can be used for MCED testing. [redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 83). [redacted]

[redacted] In addition, Dr. Cote's opinion about which technologies are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

e. Next Generation Sequencing

165. Sequencing is the process of determining the order of nucleotides, *i.e.*, the sequence, in genomic materials, such as DNA and RNA. (Cote Expert Report) ¶ 85.) The first generation of sequencing technology was based on the chain termination method developed by Dr. Frederick Sanger in 1975, often known as "Sanger Sequencing". (RX3407 (Kircher et al., 2010) at 2; RX3869 (Cote Expert Report) ¶ 85.)

Response to Finding No. 165

The proposed finding is confusing, misleading, against the weight of the evidence, and it improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is confusing because it refers to "genomic materials, such as DNA and RNA," but RNA does not represent genomic source material (save for the genome of an RNA virus, which is unlikely to be what Respondents are referring to as they struggle to make an apparently elusive point).

The proposed finding is misleading to the extent it suggests that Sanger sequencing platforms can be used for MCED testing. [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the first sentence of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 85). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard the first sentence of Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about sequencing technology is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 165.1 Applied Biosystems (ABI, now part of Thermo Fisher) introduced the automated ABI Prism 3700 DNA Analyzer in the 1990s, which allowed parallel sequencing of 96 samples of between 600 and 1,000 nucleotides in length, or a maximum of 100,000 nucleotides per run, and a very low error rate at an average of one error per 10,000–100,000 nucleotides. (RX3869 (Cote Expert Report) ¶ 85, n.75.)

Response to Finding No. 165.1

The proposed finding is misleading and against the weight of the evidence, and it improperly cites expert testimony, and Dr. Cote is not qualified to offer opinion testimony on

this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading to the extent it suggests that Sanger sequencing platforms can be used for MCED testing. [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from a footnote in Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 85 n. 75). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about sequencing technology is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

165.2 The human genome consists of approximately 3,200,000,000 basepairs (3,200 Mbp (mega-basepairs) or 3.2 Gb (giga-basepairs)) of nucleotides in about 30,000

> to 40,000 genes. (RX3869 (Cote Expert Report) ¶ 85, n.75). Many genes are thousands or tens of thousands of basepairs in length, making whole genome sequencing using Sanger sequencers a difficult task. (RX3407 (Kircher et al., 2010) at 2; RX3869 (Cote Expert Report) ¶ 85, n.75.)

Response to Finding No. 165.2

The proposed finding is vague, misleading, against the weight of the evidence, and improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because "difficult task" is ambiguous.

The proposed finding is misleading because it discusses "whole genome sequencing," which is an altogether different application than MCED testing.

The proposed finding is misleading to the extent it suggests that Sanger sequencing platforms can be used for MCED testing. [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the first sentence of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 85). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard the first sentence of Respondents' proposed finding.

[redacted]

[redacted] In addition, Dr. Cote's opinion about sequencing technology is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

166. Next-generation sequencing, also known as NGS, allows parallel sequencing of millions of small DNA fragments that are combined by software into longer, full-length sequences . (Cote Tr. 3750–51; RX3869 (Cote Expert Report) ¶ 86.) With bisulfite conversion and similar techniques, NGS sequencing can be used not only to detect genomic mutations and fragmentations, but also epigenomic modifications such as methylation. (Cote Tr. 3745; RX3869 (Cote Expert Report) ¶ 86.)

Response to Finding No. 166

The proposed finding is vague, incorrect, confusing, misleading, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because it does not define what "small" DNA fragments means and does not identify the purported "similar techniques." It is also vague because it does not define genomic "fragmentations."

The proposed finding is incorrect and confusing because not all sequencing applications involve combining small fragments "by software into longer, full-length sequences." Applications such as genome assembly involve combining small fragments into larger sequences; whereas applications such as MCED testing may not have such a step.

The proposed finding is misleading to the extent it suggests that non-Illumina NGS

platforms can be used for MCED testing. [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from a footnote in Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 86). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about NGS technology is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 166.1 Bisulfite conversion is a process in which potentially methylated DNA is treated with sodium bisulfite, leading to conversion of unmethylated cytosines (C) into uracils (U), while methylated cytosines (both 5–methylcytosine and 5–hydroxymethylcytosine) remain unchanged, thus allowing determination of DNA methylation at the singe nucleotide level. (Cote Tr. 3745; RX3869 (Cote Expert Report) ¶ 86, n.76.)

Response to Finding No. 166.1

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

167. Because cancer is caused by accumulated changes to genes that control cellular functions, a possible approach to cancer screening would be to identify all changes to such genes by interrogating all relevant gene sequences through sequencing. (PX7131 (Cote Dep. at 108–09, 125–27; RX3869 (Cote Expert Report) ¶ 87.)

Response to Finding No. 167

The proposed finding is vague and improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the terms "accumulated changes," "cellular functions," and "relevant gene sequences" are ambiguous.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his deposition testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 87). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 87). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard

Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about sequencing technology is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 167.1 With the massive parallel sequencing capability, NGS is scalable and has high throughput, and can systemically study cancer genomes in their entirety, which allows for partial or full characterization of a patient's genomic profile and thus personalized cancer management. (Cote Tr. 3750–51; RX3869 (Cote Expert Report) ¶ 87.)

Response to Finding No. 167.1

The proposed finding is misleading and against the weight of the evidence, it improperly cites expert testimony, and Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is misleading to the extent it suggests that non-Illumina NGS platforms can be used for MCED testing. [redacted] The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-

Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 87). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 87). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about NGS technology is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

> 167.2 However, NGS-based technologies also have their limitations, such as requiring investment in computer capacity and storage to handle the large volume (of tens of gigabytes) of data as well as personnel expertise to skillfully extract and comprehensively analyze and interpret the clinically important information. (RX3869 (Cote Expert Report) ¶ 87.)

Response to Finding No. 167.2

The proposed finding is vague and improperly cites expert testimony. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the opening word "however" is provided without

context. Additionally, Respondents do not specify the amount of investment required for computer capacity and storage as well as personnel expertise.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 87). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 87). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] In addition, Dr. Cote's opinion about NGS technology is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

168. GRAIL's Galleri is the only NGS-based early cancer screening test currently on the market in the United States and is currently marketed at $949 per test. (Bishop (GRAIL) Tr. 1401; RX3292 (GRAIL).) No NGS-based early cancer screening tests have obtained FDA approval or mechanisms for reimbursement, either by Medicare or by private payors. (PX7086 (Cance (ACS) Dep.) at 49, 58; RX3869 (Cote Expert Report) ¶ 88.)

Response to Finding No. 168

The proposed finding is misleading, and Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

- [redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 88). [redacted]

[redacted] In addition, Dr. Cote's opinion about the process and timeline for developing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

f. Multiomics

169. An increasing number of companies are developing "multi-omic" tests which combine information from multiple analytes, including DNA (genome), RNA (transcriptome) and protein (proteome) for increased sensitivity in cancer detection. [redacted]; RX3869 (Cote Expert Report) ¶ 89.)

Response to Finding No. 169

[redacted]

[redacted]

169.1 For example, Exact/Thrive's CancerSEEK pipeline screening test assesses levels of nine protein biomarkers as well as mutations in 16 genes for the early detection of cancers of multiple organs: ovary, liver, stomach, pancreas, esophagus, kidney,

bladder, colorectum, lung or breast, in addition to a PET-CT step for positive test results. (RX3419 (Lennon et al., 2020) at 6; Cote Tr. 3811–12.)

Response to Finding No. 169.1

The proposed finding is vague, misleading, and against the weight of the evidence. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

The proposed finding is vague because the opening phrase "for example" is provided without context.

The proposed finding is misleading to the extent it suggests that proteomics is an alternative or replacement for Illumina NGS for MCED testing. [redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 89). [redacted] In addition, Dr. Cote's opinion about Exact's process and timeline for developing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed

publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 169.2 Freenome similarly combines data from whole-genome sequencing, DNA methylation, and protein quantification for the early detection of colorectal cancer from a blood test. (RX3426 (Lin et al., 2021) at 1; RX0111 (Putcha et al., 2020) at 1); Cote Tr. 3844.)

Response to Finding No. 169.2

The proposed finding is vague and misleading. The proposed finding is vague because the term "protein quantification" is undefined, and the term "similarly" is provided without context.

The proposed finding is misleading to the extent it suggests that proteomics is an alternative or replacement for Illumina NGS for MCED testing. [redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 89). [redacted] In addition, Dr.

Cote's opinion about Freenome's process and timeline for developing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

169.3 PrognomiQ, a recent spin-off of Seer, is also developing early cancer screening tests by combining proteomic information, obtainable using Seer's Proteograph platform, with genomic, metabolomic, and other health data. (RX3587 (PrognomiQ) at 1–2; RX3869 (Cote Expert Report) ¶ 89.)

Response to Finding No. 169.3

The proposed finding misattributes the source of a document and is vague, misleading, and against the weight of the evidence. Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote is not reliable.

Complaint Counsel objects to the attribution of RX3587 (which Respondents appear to have captured from PorgnomiQ's website) to PrognomiQ as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. No discovery was taken in this matter from PrognomiQ, and the document was not produced by PrognomiQ. The document constitutes hearsay. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is vague because the terms "proteomic information" and "genomic, metabolomic, and other health data" are ambiguous.

The proposed finding is misleading to the extent it suggests that proteomics is an alternative or replacement for Illumina NGS for MCED testing. [redacted]

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. (RX3869 (Cote Report) ¶ 89). Dr. Cote is not qualified to provide expert opinion testimony about PrognomiQ's process and timeline for developing a multicancer screening test because he has no experience developing such tests (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about PrognomiQ's process and timeline for developing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

C. Features of Cancer Screening Tests

170. The metrics that may be used to assess the performance of oncology tests, including blood-based early stage cancer screening tests include sensitivity, specificity and cancer signal of origin (also known as tissue of origin) analyses. [redacted]; Cote Tr. 3778–82; RX3869 (Cote Expert Report) ¶ 90.)

Response to Finding No. 170

[redacted]

171. In addition to the number of cancers that a screening test is capable of detecting, these metrics provide further grounds for differentiating between different tests and defining whether physicians are likely to substitute one test for another. (Cote Tr. 3778–82; RX3869 (Cote Expert Report) ¶ 90.) In addition to these technical metrics, physicians may also evaluate and select tests based on other factors, such as the ease of using the test. (RX3869 (Cote Expert Report) ¶ 90.)

Response to Finding No. 171

The proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support

factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 90. And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 90). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "these metrics" and "these technical metrics" are provided without context. Additionally, the term "other factors" is ambiguous and

vague.

172. Sensitivity. Sensitivity, also called the true positive rate, measures the proportion of actual positive samples that are correctly identified as such, or how often a test correctly generates a positive result for people who have the condition for which they are being tested. (RX3869 (Cote Expert Report) ¶ 91.) Low sensitivity leads to high *false negative* rates. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 91.)

Response to Finding No. 172

Complaint Counsel does not disagree with the proposed finding.

172.1 A concept that is related to false negative rate is the Negative Predictive Value ("NPV"), which is the percentage of patients with a negative test who do not have cancer. (RX3869 (Cote Expert Report) ¶ 91.) NPV represent the probability a patient does not have cancer when the test result is negative. (RX3869 (Cote Expert Report) ¶ 91.)

Response to Finding No. 172.1

Complaint Counsel does not disagree with the proposed finding.

172.2 Compared with therapy selection tests where the patient has developed tumors, early stage cancer patients have only small amounts of cancer cells in the body and only a minute amount of materials from cancer, including circulating tumor DNA (ctDNA), mRNA, protein, and circulating cancer cells, in the blood. (RX3303 (Haque et al., 2017) at 3); Cote Tr. 3735–36.)

Response to Finding No. 172.2

Complaint Counsel objects to the proposed finding because it is vague and misleading.

The proposed finding is vague because the terms "small amounts" and "minute amount" are undefined. The proposed finding is also vague because it does not identify all of the "materials from cancer" referenced.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities. Therefore, this Court should disregard the proposed finding.

172.3 Therefore, a relatively high sensitivity is an important requirement for an early cancer screening test designed for use in asymptomatic individuals. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 92.)

Response to Finding No. 172.3

Complaint Counsel objects to the proposed finding because it is vague, confusing, unsupported, and it improperly cites expert testimony.

The proposed finding is vague because the term "relatively high sensitivity" is imprecise.

The proposed finding is confusing because an "early cancer screening test" is by definition "designed for use in asymptomatic individuals."

The proposed finding is unsupported because the only sources cited are Dr. Cote's trial testimony and expert report, neither of which, in turn, provides any additional support for

This Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source to establish a purported fact in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

173. Specificity. Specificity, or the true negative rate, measures the proportion of actual negative samples that are correctly identified as such, or how often a test correctly generates a negative result for people not having the condition for which they are being tested. (Cote Tr. 3778–3781; RX3869 (Cote Expert Report) ¶ 93.) Low specificity leads to high *false positive* rates. (Cote Tr. 3778–3781; RX3869 (Cote Expert Report) ¶ 93.)

Response to Finding No. 173

Complaint Counsel does not disagree with the proposed finding.

173.1 [redacted]

Response to Finding No. 173.1

[redacted]

[redacted]

173.2 [redacted]

Response to Finding No. 173.2

[redacted]

[redacted]

174. Positive Predictive Value. A concept that is related to false positive rate is the Positive Predictive Value ("PPV"), which is the percentage of patients with a positive test who actually have cancer. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93.)

Response to Finding No. 174

Complaint Counsel does not disagree with the proposed finding.

174.1 PPV represent the probability a patient has cancer when the test result is positive. (Cote Tr. 3779; RX3869 (Cote Expert Report) ¶ 93.) The PPV is a particularly important metric for cancer screening tests. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93.)

Response to Finding No. 174.1

Complaint Counsel does not disagree with the first sentence of the proposed finding.

The remainder of the proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 93). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 93). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance

metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the term "particularly important" is ambiguous.

175. Because a cancer screening test is a test used in the general population, *i.e.*, healthy individuals, the baseline rate of cancer in that population is very low. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93.) As a result, the rate of true positives—individuals with cancer in the population—will be extremely low, around 4 in 1000 individuals. (RX3501 (National Cancer Institute, Cancer Statistics).)

Response to Finding No. 175

The proposed finding is misleading, improper, unreliable, and vague. Respondents' citation to RX3501 is in contravention of this Court's order that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3501 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. Thus, the Court should disregard this proposed evidence. Respondents' citation to RX3501 is also misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was

copied and pasted verbatim. (RX3869 (Cote Report) ¶ 93).

The first sentence of Respondents' proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this portion of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 93). Respondents improperly rely only on Dr. Cote's testimony in contravention of this Court's Order, and therefore this Court should disregard the first sentence of Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the term "very low" is ambiguous. It is unclear what constitutes a "very low" baseline rate of cancer. Therefore, this Court should disregard the

proposed finding.

176. Therefore, even if a test is highly specific with a low false positive rate, the likelihood that a person with a positive test result actually has cancer may still be relatively low given the low baseline rate of cancer in the population. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93).

Response to Finding No. 176

The proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 93). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 93). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that

his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "highly specific," "low false positive rate," "relatively low," and "low baseline rate" are all ambiguous. Additionally, the opening phrase "therefore" is provided without context.

> 176.1 For example, a specificity of 99.5% still translates into about a 40– 50% PPV—one of every two individuals with a positive test result would be a false positive. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93.)

Response to Finding No. 176.1

Complaint Counsel objects to the proposed finding because it is unsupported, vague, confusing, misleading, and noncompliant with Part 3 rules, and because Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because "about a 40– 50% PPV" is imprecise and unclear.

The proposed finding is vague and confusing because calculating PPV requires values for test specificity, test sensitivity, and disease prevalence. The proposed finding only includes a value for test specificity; it does not include values for test sensitivity or disease prevalence.

The proposed finding is unsupported because it does not provide the test sensitivity or disease prevalence values required to calculate PPV, nor does it set forth the calculation underlying the purported example. Accordingly, there is no basis for the claim that "a specificity of 99.5%" translates into "about a 40– 50% PPV." Respondents cite Dr. Cote's report and testimony as support, but neither source supplies the missing values nor performs the calculation underlying the purported example. Dr. Cote's private calculation of PPV violates the

Part 3 rules (*see* 16 C.F.R. § 3.31A(c) (requiring that expert reports "contain a complete statement of all opinions to be expressed and the basis and reasons therefor" as well as the "data, materials, or other information considered by the witness in forming the opinions")) and prevents this Court from even assessing his method. This Court should reject this purported expert testimony as noncompliant, unsupported, and unreliable.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order workup for patients who have tested positive for cancer. (Cote, Tr. 3978-79). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about the performance attributes of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

177. Both false positive results and false negative results of a cancer screening test will have significant negative impact on the patient's well-being. ([redacted] 3778–81, 3814, [redacted]; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep. at 90–91.)

Response to Finding No. 177

Complaint Counsel has no specific response to the proposed finding.

178. False negative findings cause physicians to not diagnose a cancer that either is already causing or will soon cause harm to patients, and miss precious early treatment opportunities; false positive results leads to unnecessary follow-ups and even often harmful procedures to rule out cancer, let alone the severe emotional distress to patients and their families. [redacted] 3778–81, 3814, [redacted]; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep. at 90–91.)

Response to Finding No. 178

Complaint Counsel has no specific response to the proposed finding.

179. Therefore, high specificity, *i.e.*, low false positive rates, is also important for a cancer screening test. ([redacted] 3778–81, 3814, [redacted]; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep. at 90–91.)

Response to Finding No. 179

The proposed finding is vague because the terms "high specificity" and "low false positive rates" are ambiguous. Additionally, the terms "therefore" and "also" are provided without context. Therefore, this Court should disregard the proposed finding.

180. However, there is typically a tradeoff between specificity and sensitivity. (RX3869 (Cote Expert Report) ¶ 95.) Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (RX3869 (Cote Expert Report) ¶ 95.)

Response to Finding No. 180

The proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 95). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 95).

Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because it does not specify what is meant by the "same conditions," the terms "typically," "tradeoff," and "may often have" are ambiguous, and the opening word "however" is provided without context.

> 180.1 Existing single cancer screening tests typically have very high sensitivity rates and correspondingly lower specificity/higher false positive rates. (RX3869 (Cote Expert Report) ¶ 95.)

Response to Finding No. 180.1

The proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's

expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 95). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 95). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "very high sensitivity rates" and "typically" are ambiguous. Additionally, the proposed finding fails to provide examples of any existing single cancer screening tests with very high sensitivity rates.

> 180.2 For example, a colonoscopy has a sensitivity of 92.5% and a specificity of 73.2%. (RX3393 (Issa & Noureddine 2017) at 9.) Cologuard has a sensitivity of 92.3% and a specificity of 86.6%. (RX3222 (FDA) at 19.)

Response to Finding No. 180.2

The proposed finding is misleading because Respondents fails to identify Dr. Cote's report as the source from which the proposed finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 95). Therefore, this Court should disregard the proposed finding.

> 180.3 Mammography for breast cancer screening has a sensitivity of 86.9% and a specificity of 88.9%, and the PPV is only 4%, meaning that only 4 of 100 positive tests actually identify breast cancer. (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 4.)

Response to Finding No. 180.3

The proposed finding is misleading because Respondents fails to identify Dr. Cote's report as the source from which the proposed finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 95). Therefore, this Court should disregard the proposed finding.

> 180.4 This means that most patients with a "positive" mammography result will have to undergo further invasive testing, but will end up with a negative cancer diagnosis. (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 6.)

Response to Finding No. 180.4

The proposed finding is unsupported, misleading, and vague. The proposed finding is unsupported because RX3079 does not mention further invasive testing for patients with a positive mammography result, only a "recommendation for immediate follow-up." (RX3079 at 1 (Breast Cancer Surveillance Consortium)).

Respondents' citation to RX3442 is misleading to the extent that the proposed finding suggests that false positives are a harm to patients. The article explains that: "There is disagreement as to whether false positives should be classified as a harm of cancer screening. One point of view is that any test, including the diagnostic evaluation tests that accompany a false positive, is a test worth having if it rules out cancer. The other point of view is that false positives are a harm of cancer screening as they cause patients to worry unnecessarily and to receive unneeded medical tests and procedures, some of which can be risky." (RX3442 at 6

(Marcus PM, Assessment of Cancer Screening: A Primer, National Cancer Institute (2019)). Only one point of view is presented in the proposed finding. The proposed finding is also misleading because Respondents fails to identify Dr. Cote's report as the source from which the proposed finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 95).

The proposed finding is vague because the opening word "this" is provided out of context. Additionally, Respondents fail to specify what further testing patients will have to undergo or how it will be invasive. Therefore, this Court should disregard the proposed finding.

181. A test developer focusing on a cancer screening test for a large number of cancer types must focus on attaining a very high specificity rate, and a high PPV, which will often result in correspondingly lower sensitivity rates. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 95.) This is because when screening the general population of individuals over age 50, or those with a family history of cancer, it is critical that the morbidity and expense of following up on a false positive test is minimized. (RX3869 (Cote Expert Report) ¶ 95.)

Response to Finding No. 181

The proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 95). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 95). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance

metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "large number of cancer types," "often result," and "following up" are ambiguous.

> 181.1 By contrast, a test developer focusing on a single cancer screening test or a test directed to only a handful of targeted cancer types may elect to focus on sensitivity more than specificity. (PX6097 (Abrams Expert Report) ¶ 29; RX3869 (Cote Expert Report) ¶ 95.) This again points out the fundamental differences in design that are likely to differentiate tests used to detect early stage cancer. (Cote Tr. 3778–81, 3868–69; RX3869 (Cote Expert Report) ¶ 95.)

Response to Finding No. 181.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, and unsupported, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague because it is unclear what "focusing on" a single cancer screening test means, and it does not define "only a handful." The proposed finding is also vague in its use of "may."

The proposed finding is misleading to the extent it suggests that differences among MCED tests will prevent them from competing in the same product market**.** [redacted]

[redacted]

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order workup for patients who have tested positive for cancer. (Cote, Tr. 3978-79). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about the performance attributes of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

182. Cancer Signal of Origin. A blood test, unlike a biopsy of a specific organ, does not automatically indicate the possible cancer signal of origin for the cancer to be detected. (Cote Tr. 3782; RX3869 (Cote Expert Report) ¶ 96.)

Response to Finding No. 182

The proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 96). And, moreover, the quoted

portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 96). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "blood test" and "possible signal of origin" are ambiguous, and it does not explain what it means that a test "does not automatically indicate" the possible signal of origin means. It is unclear if the proposed finding refers to blood-based MCED tests specifically or blood tests generally.

> 182.1 Therefore, for a blood-based multi-cancer screening test to be most effective, identification of the possible cancer signal of origin is highly desirable. (RX3869 (Cote Expert Report) ¶ 96.)

Response to Finding No. 182.1

The proposed finding is improper, unreliable, and vague. The proposed finding is

improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 96). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 96). Respondents improperly rely only on Dr. Cote's expert opinion in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "most effective," "highly desirable," and "possible cancer signal of origin" are ambiguous. Additionally, the opening word

"therefore" is provided without context.

182.2 [redacted]

Response to Finding No. 182.2

[redacted]

182.3 Identification of a cancer signal of origin ensures that the necessary follow-up from a positive test result is efficiently directed to a targeted imaging step or a biopsy, such that those patients who receive a positive test result will not suffer undue anxiety waiting for further testing. (RX3869 (Cote Expert Report) ¶ 96.)

Response to Finding No. 182.3

The proposed finding is misleading, unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from

Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 96). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 96). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted] Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order workup for patients who have tested positive for cancer. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to

nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the term "targeted imaging step" is undefined, and the term "undue anxiety" is ambiguous.

> 182.4 Importantly, a cancer screening test that is capable of detecting multiple cancer types that returns a positive result, but does not indicate the possible cancer signal of origin, would result in a possibly extensive, invasive and expensive workup to rule in or out the presence of cancer. ([redacted] 3782, 3814, [redacted] RX3869 (Cote Expert Report) ¶ 97.)

Response to Finding No. 182.4

The proposed finding is misleading, unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 97). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 97). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

[redacted]

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order workup for patients who have tested positive for cancer. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the term "possibly extensive, invasive, and expensive workup" is ambiguous. Respondents fail to specify what kind of workup patients might have to undergo or how it will be extensive, invasive, and expensive

> 182.5 No cancer screening test will be perfect, and even at the extremely high PPV of 50%, only one half of the patients with a positive screening test will actually have cancer. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 97.)

Response to Finding No. 182.5

The proposed finding is unreliable and improperly cites expert testimony. The proposed

finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 97). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 97). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

182.6 In the above example of a test with a PPV of 50%, the workup would likely be even more prolonged, invasive and expensive for the patients who do not have cancer than for a patient who does have cancer, as the patient without cancer would be

forced to undergo a particularly extensive workup to definitively rule out cancer. ([redacted] 3782, 3814, [redacted]; RX3869 (Cote Expert Report) ¶ 97.)

Response to Finding No. 182.6

The proposed finding is unreliable, vague, and improperly cites expert testimony. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 97). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 97). Respondents improperly rely only on Dr. Cote's expert testimony in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order workup for patients who have tested positive for cancer. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not

accord Dr. Cote's opinion any weight.

The proposed finding is vague because Respondents fail to specify what kind of workup patients might have to undergo or how it will be prolonged, invasive, and expensive.

> 182.7 On the other hand, a multi-cancer screening test that *does* indicate the possible cancer signal of origin will require much less extensive and more focused initial follow-up. (Cote Tr. 3782; RX3869 (Cote Expert Report) ¶ 97.)

Response to Finding No. 182.7

Complaint Counsel objects to the proposed finding because it is vague, misleading, and incomplete, Dr. Cote is not qualified to offer opinion testimony on this topic, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not define what it means to indicate the "possible" cancer signal of origin.

[redacted]

The proposed finding is incomplete and misleading to the extent that it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT. [redacted]

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order workup for patients who have tested positive for cancer. (Cote, Tr. 3978-79). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about the performance attributes of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 182.8 Providing accurate cancer signal of origin to facilitate cancer diagnosis will improve clinical utility and patient compliance, thus impact decision-making by physicians using cancer screening tests. (PX6097 (Abrams Expert Report), ¶¶ 10.g, 22, 27; RX3869 (Cote Expert Report) ¶ 97–98; Cote Tr. 3782.)

Response to Finding No. 182.8

The proposed finding is improper, unreliable, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report, Dr. Cote's trial testimony, and Dr. Abrams's report to

support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 97). Respondents improperly rely only on Dr. Cote's and Dr. Abrams's expert opinions in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the performance metrics for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order cancer screening tests for patients. (Cote, Tr. 3978-79). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the performance metrics of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

[redacted]

The proposed finding is vague because the terms "clinical utility" and "patient compliance" are undefined, and the term "impact" is ambiguous. The proposed finding is also

vague because it does not specify the manner of "providing accurate cancer signal of origin."

183. Detecting Multiple Cancers. [redacted]

Response to Finding No. 183

[redacted]

[redacted]

183.1 [redacted]

Response to Finding No. 183.1

[redacted]

[redacted]

D. Regulatory Requirements

184. The FDA is charged with protecting the public health by assuring the safety, effectiveness, and security of medical devices, including diagnostic and screening tests. (RX3006 (FDA); PX7099 (Febbo (Illumina) Dep. at 83–84).)

Response to Finding No. 184

The proposed finding is vague and unsupported and violates the Court's Order. It is unsupported because it includes multiple references to terms and phrases that appear nowhere in the cited sources. Neither RX3066, which appears to be a printout of a portion of the FDA's website, nor the cited testimony of Dr. Febbo mentions anything about the "security" of medical devices. Neither RX3066 nor the cited testimony of Dr. Febbo mentions the terms "screening" or "screening tests." The proposed finding is vague because "charged" and "assuring" are not defined, nor are the terms "security" or "screening tests" which appear in the proposed finding but not in the cited sources. Additionally, this Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3006 is a multi-page document; Respondents fail to provide to provide a citation to any specific page

number of page range in RX3006 in contravention of the Court's Order. Finally, the FDA did not "produce" RX3006; the proposed finding is misleading to the extent that implies direct production by the FDA in connection with this proceeding. Therefore, this Court should disregard the proposed finding.

185. Medical devices marketed in the United States must adhere to regulatory requirements as set forth in the Federal Food, Drug, and Cosmetic Act and 21 CFR § 1–58, 800–1299. (RX3326 (FDA) at 1.) Devices are classified as Class I, II or III, where each class corresponds with a differing degree of risk. (RX3326 (FDA) at 2.)

Response to Finding No. 185

RX3326 appears to be a printout of a portion of the FDA's website. The FDA did not "produce" RX3326; the proposed finding is misleading to the extent that implies direct production by the FDA in connection with this proceeding. Beyond that, Complaint Counsel does not disagree with the proposed finding.

185.1 Class I devices are those that present the lowest risk, with minimal potential for patient harm. (RX3326 (FDA) at 2.)

Response to Finding No. 185.1

RX3326 appears to be a printout of a portion of the FDA's website. The FDA did not "produce" RX3326; the proposed finding is misleading to the extent that implies direct production by the FDA in connection with this proceeding. Beyond that, Complaint Counsel does not disagree with the proposed finding.

185.2 Class II devices represent a moderate risk, and Class III devices represent the highest level of risk, used in scenarios where the device is used to sustain or support life, the device is implanted, or the device presents potential unreasonable risk of illness or injury. (RX3326 (FDA) at 2; RX6001 (Deverka Trial Dep. at 39); RX3867 (Deverka Expert Report) ¶ 32.)

Response to Finding No. 185.2

RX3326 appears to be a printout of a portion of the FDA's website. The FDA did not "produce" RX3326, and the proposed finding is misleading to the extent that implies direct

production by the FDA in connection with this proceeding. Beyond that, Complaint Counsel does not disagree with the proposed finding.

186. Depending on the Class of device, the device may require a different level of FDA premarket clearance or approval, or may not require FDA premarket submission at all.' (RX3326 (FDA) at 3; RX3416 (FDA) at 1.)

Response to Finding No. 186

The proposed finding is vague and confusing. The proposed finding is vague because the phrase "different level of FDA premarket clearance or approval" is undefined. The proposed finding is confusing because it is unclear what baseline "different level" is being compared against. The proposed finding is also vague and confusing because no context is provided for the phrase "may require" and so it is unclear whether Respondents are referencing requirements for product development, clinical testing, LDT sales, or FDA approval. Additionally, RX3326 and RX3416 appear to be printouts of a portion of the FDA's website. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. The FDA did not "produce" RX3326 or RX3416; the proposed finding is misleading to the extent that implies direct production by the FDA in connection with this proceeding. Therefore, this Court should disregard the proposed finding.

187. A company can offer a clinical test to patients in three ways: as a Laboratory Developed Test ("LDT"), as a single-site IVD test, or an IVD distributed kit. (Goswami (Illumina) Tr. 3185–87.)

Response to Finding No. 187

The proposed finding is vague and incomplete. The proposed finding is vague because the context for term "can offer" is unclear. To the extent the finding is intended to describe regulatory requirements, the finding is incomplete in that it does not specify that the listed avenues for offering a clinical test are specific to the U.S. regulatory system. Therefore, this

Court should disregard the proposed finding.

187.1 LDTs are the most common offering and involve a company clinically and analytically validating the test and then running the test in a single laboratory that has received CLIA/CAP certification. (Goswami (Illumina) Tr. 3185, 3195–96.)

Response to Finding No. 187.1

The proposed finding is vague, unsupported, and incomplete. The proposed finding is vague because the terms "most common" and "offering" are undefined. It is unclear whether "most common" refers to the regulatory strategy undertaken by most labs, "most common" in the sense that most total "offerings" used by consumers are LDTs, or something else entirely. The proposed finding is unsupported because Mr. Goswami lacks foundation because he has no personal knowledge of what is "most common" among companies other than Illumina and no other foundation was established for him to make such a statement. The finding is also vague in that it does not specify the meaning of the phrase "clinically and analytically validating." The finding is incomplete in that it omits that LDTs are self-validated by the labs themselves. *See* CCFF ¶¶ 498. For the above reasons, this proposed finding of fact should be disregarded.

187.1.1 While LDTs do not undergo FDA clearance or approval processes, they are regulated by the Clinical Laboratory Improvements Amendments (CLIA) program, which is implemented via a division of the Centers of Medicare and Medicaid Services (CMS) called the Division of Clinical Laboratory Improvement & Quality. (RX3325 (CMS); PX7113 (Rabinowitz (Natera) Dep. at 382); PX7077 (Chahine (Helio) Dep. at 1028); RX3867 (Deverka Expert Report) ¶ 34.)

Response to Finding No. 187.1.1

The proposed finding is vague and incomplete. The proposed finding is vague because it does not define the phrase "regulated by the Clinical Laboratory Improvements Amendments (CLIA) program." The finding is incomplete in that it omits that the compliance certified by the Centers for Medicare & Medicaid Services ("CMS") is the CLIA compliance of the laboratories themselves, *see* CCFF ¶¶ 497, and that LDTs are self-validated by the labs in which the testing is

performed. CCFF ¶¶ 498. Complaint Counsel does not disagree that tests sold as LDTs have not received FDA approval or clearance but notes, for completeness, that LDTs may subsequently receive FDA approval or clearance.

> 187.1.2 Despite not being approved or cleared by the FDA, LDTs still must meet rigorous quality and safety standards for clinical diagnostic testing because it must be run in a laboratory with CLIA certification. (RX3325 (CMS); RX3867 (Deverka Expert Report) ¶ 34.)

Response to Finding No. 187.1.2

The proposed finding is unsupported as it is based on improper expert opinion testimony and citation to an irrelevant website printout that fails to establish the underlying factual matters asserted. RX3325 appears to be a printout of a portion of CMS's website that, oddly, describes the administrative process related to submission of a CLIA application form. RX3325 mentions nothing about quality or safety standards for clinical diagnostic testing – rigorous or otherwise. The only other source cited for the proposed finding is Dr. Deverka's expert report. (In fact, the text of the proposed finding is simply pasted in from Dr. Deverka's report). This Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Deverka in contravention of this Court's Order. Moreover, Dr. Deverka lacks the foundation and requisite expertise to opine on the CLIA certification process for of laboratories. Dr. Deverka readily acknowledges that she is not a regulatory expert, (RX6001 (Deverka Trial Dep. at 126), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126). The only support Dr. Deverka herself cites for her statement is RX3325, which as noted above fails to support the proposed finding. Accordingly, neither RX3325 nor Dr. Deverka's report support the proposed finding. This Court should disregard this evidence. Additionally,

this Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3325 is a multi-page document; Respondents fail to provide to provide a citation to any specific page number of page range in the document in contravention of the Court's Order. Finally, CMS did not "produce" RX3325; the proposed finding is misleading to the extent that implies direct production by the CMS in connection with this proceeding. For all the above reasons, this proposed finding of fact should be disregarded.

> 187.1.3 Labs undergo routine audits in which the clinical data supporting their tests and the claims that they put on their reports are reviewed and put their CLIA license at risk if they don't have sufficient data supporting their tests. (Febbo (Illumina) Tr. 4322–23.).

Response to Finding No. 187.1.3

The proposed finding is vague, unreliable, and relies solely on the self-serving testimony of a party executive. The proposed finding is vague because the terms "routine," "audits," "clinical data," "supporting," and "claims that they put on their reports," "reviewed," "at risk," and "sufficient" are undefined. The proposed finding is unreliable because Dr. Febbo does not have a foundation to speak to the experience of "labs" generally. Finally, Respondents cite only to the self-serving testimony of an Illumina Grail executive for factual propositions that are uncorroborated by any ordinary course documents. Given the inherent vagueness and unreliability of this testimony as well as the lack of foundation, this proposed finding of fact should be disregarded.

> 187.2 Single-site IVDs are tests that have been FDA-approved, but only can only be run in a single lab. (Goswami (Illumina) Tr. 3186.)

Response to Finding No. 187.2

Complaint Counsel does not disagree with the proposed finding.

187.3 An distributed IVD test or IVD kit involves a kit that is developed and manufactured by a test manufacturer which, after receiving FDA approval, can be run in various labs provided that the labs are CLIA/CAP certified. (Goswami (Illumina) Tr. 3186–87.)

Response to Finding No. 187.3

Complaint Counsel has no specific response to this proposed finding.

187.3.1 The manufacturer of an IVD distributed test, not the lab running the test, bears the burden of continuing to manufacture, distribute and support the test in accordance with FDA guidelines. (Goswami (Illumina) Tr. 3187.)

Response to Finding No. 187.3.1

Complaint Counsel has no specific response to this proposed finding.

187.3.2 IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200.)

Response to Finding No. 187.3.2

The proposed finding is vague and unreliable. The proposed finding is vague because "precious samples," "shipping challenges," and "fast turnaround" are undefined. The proposed finding is unreliable because it represents opinion testimony from a fact witness purporting to speak beyond his personalized experience or the experience of Illumina; Mr. Goswami does not have foundation to opine on the generalized circumstances for which IVD kits "are most suitable." Therefore, this Court should disregard the proposed finding.

188. The below table summarizes the minimum required regulatory submission type required for diagnostic tests depending on the type and class of device. (RX3326 (FDA) at 1–4; RX3416 (FDA) at 1; RX3867 (Deverka Expert Report) ¶ 33.)

Table 1

Regulatory Submission	Eligible Devices	Governing Body	Regulatory Terminology
LDT	Tests that are designed, manufactured and used in a single lab (including RUO/IUO kits) do not require FDA premarket submission. LDTs may be widely	CLIA (CMS)	Not currently reviewed by FDA

Regulatory Submission	Eligible Devices	Governing Body	Regulatory Terminology
	accessible even though all analysis is conducted in a central lab that meets CLIA certification standards.		
510(k)	Required for some Class I and most Class II devices. Manufacturers must demonstrate that the device is substantially equivalent (SE) to (i.e. as safe and effective as) a legally marketed predicate device.	FDA	FDA cleared
De Novo Classification	Provides pathway for Class I and II devices for which there is no legally marketed predicate device.	FDA	FDA cleared
PMA	Class III devices and companion diagnostics (CDxs) require a premarket approval (PMA). The PMA must contain sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).	FDA	FDA approved

Response to Finding No. 188

The proposed finding, which consists of a chart pasted verbatim from Dr. Deverka's report, is unsupported and misleading and violates the Court's Post-Trial Order in multiple ways. First, this Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous distinct proposed findings of fact together into a chart without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46.

Second, Respondents cite Dr. Deverka as a source to support factual statements about regulatory submissions. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Respondents citation to Dr. Deverka contravenes this Court's Order. This Court should disregard this evidence. Dr. Deverka lacks foundation to testify as an expert regarding regulatory matters. Dr. Deverka testified during her trial deposition that she is neither an FDA

expert nor a regulatory expert. (RX6001 (Deverka Trial Dep. at 126)). Dr. Deverka has never worked at the FDA, Centers for Medicare and Medicaid Services, or at the United States Preventive Services Task Force ("USPSTF"). (RX6001 (Deverka Trial Dep. at 126)).

Third, this Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. The FDA did not "produce" RX3326 or RX3416; the proposed finding is misleading to the extent that it implies direct production by the FDA in connection with this proceeding. Even setting that issue aside, RX3326 and RX3416 are not the actual sources of the material contained in Respondents' chart. [redacted] In the absence of specific citations for specific factual propositions, Respondents' proposed finding should be disregarded as improper and unsupported.

189. A company seeking FDA approval for an in-vitro diagnostic (IVD)—i.e., a test of human tissue or blood samples that is performed outside the body—for any test of a life threatening disease, such as cancer, would need premarket approval. (RX3867 (Deverka Expert Report) ¶ 35.)

Response to Finding No. 189

[redacted]

[redacted]

190. Galleri would be classified as a Class III device requiring premarket approval before it could be commercialized as an FDA-approved test. (Febbo (Illumina) Tr. 4445.)

Response to Finding No. 190

Complaint Counsel does not disagree with the proposed finding.

191. Premarket approval (PMA) is the "most stringent type of device application required by FDA." (RX3585 (FDA Approval) at 10.) It often requires significant preparation and voluminous amounts of data, including in-depth review of the technical features of a device and extensive data from clinical trials to demonstrate the efficacy and safety of the device. (RX3867 (Deverka Expert Report) ¶ 35.)

Response to Finding No. 191

The proposed finding is improper, vague, unreliable, and misleading. Complaint Counsel objects to Respondents' misattribution of RX3585 to suggest that it was produced by the FDA, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3 ("When citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document."). The document was not produced by the FDA. Rather, Respondents themselves appear simply to have printed out a page from "drugwatch.com." The document itself constitutes unreliable hearsay. It is an untested statement from a random internet site. Given the inherent unreliable nature of the document, it lacks probative value (*see* Rule 4.43(b)). This court should disregard RX3585. Moreover, Respondents' misattribution of the document to suggest that it was produced by the FDA is itself misleading.

[redacted]

[redacted]

Even if the proposed finding were considered opinion-based, Dr. Deverka is not qualified to provide expert opinion testimony about the FDA's regulatory process. Dr. Deverka testified during her trial deposition that she is neither an FDA expert nor a regulatory expert. (RX6001 (Deverka Trial Dep. at 126)). This Court should not accord Dr. Deverka's opinion any weight and should disregard the proposed finding.

192. PMA submissions not only take significant time, investment and resources to prepare, but they also take time for the FDA to review. (RX3867 (Deverka Expert Report) ¶ 35.) PMA submission requires a rigorous evidence review. (RX3569 (FDA) at 1; RX3867 (Deverka Expert Report) ¶ 35.)

Response to Finding No. 192

While the term "significant" is vague and ambiguous, Complaint Counsel does not disagree that the PMA submissions require time, investment, and resources to prepare. And while the term "rigorous" is vague and ambiguous, Complaint Counsel does not disagree that PMA approval exceeds the requirements to sell a device as an LDT. (*See* CCFF ¶¶ 506-535).

Beyond those specific points, the Court should disregard the proposed finding.

Complaint Counsel notes that the proposed finding relies on improper expert opinion.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Deverka as the only source of evidence supporting the fact that PMA approval often requires significant preparation and voluminous amounts of data. Even if the proposed finding were considered opinion-based, Dr. Deverka is not qualified to provide expert opinion testimony about the FDA's regulatory process. Dr. Deverka testified during her trial deposition that she is neither an FDA expert nor a regulatory expert. (RX6001 (Deverka Trial Dep. at 126)). This Court should not accord Dr. Deverka's opinion weight.

The second sentence of the proposed finding cites to RX3569. RX3569 does not specifically state anywhere that "PMA submission requires a rigorous evidence review." [redacted] But, as noted above, Dr. Deverka is not qualified to speak to the requirements of PMA submission as either a fact or expert witness. The Court should not accord Dr. Deverka's opinion any weight.

Finally, Complaint Counsel notes that the FDA did not "produce" RX3006; the proposed finding is misleading to the extent that implies direct production by the FDA in connection with this proceeding.

E. Market Access: Key Factors and Stakeholders

193. The commercial availability of a novel medical device, however promising, will not result in broad patient access without reimbursement by payors and adoption by stakeholders. (RX6001 (Deverka Trial Dep. at 30–31); RX3867 (Deverka Expert Report) ¶ 29.) Test manufacturers must engage in a multi-pronged campaign to obtain reimbursement of a new test before it can obtain widespread adoption. (RX6001 (Deverka Trial Dep. at 30–31); RX3867 (Deverka Expert Report) ¶ 29.)

Response to Finding No. 193

The proposed finding is vague because the terms "stakeholders," "multi-pronged," are

ambiguous. Complaint Counsel does not disagree that obtaining coverage from Medicare and private insurers is important to achieve broad patient access for MCED tests. (*See* CCFF ¶¶ 552-563).

194. Test manufacturers must take into account a range of considerations when bringing a new test to market, including reimbursement by payors, development of clinical evidence, obtaining regulatory approvals, and adoption by relevant stakeholders. (RX6001 (Deverka Trial Dep. at 31–32, 33–34); RX3867 (Deverka Expert Report) ¶ 30.)

Response to Finding No. 194

The proposed finding is vague because the terms "range of considerations," "bringing . . . to market," and "relevant stakeholders" are ambiguous. Therefore, this Court should disregard the proposed finding.

195. The table below provides an overview of each factor, which is described in more detail below. (RX6001 (Deverka Trial Dep. at 31–32, 33–34); RX3867 (Deverka Expert Report) ¶ 30.)

Table 2

Factor	**Key Components**
Evidence	Analytical Validity Evidence
Development	Clinical Validity Evidence
	Clinical Utility Evidence
	Health Economic Evidence
	Engagement with Payors
Regulatory	Approval or Clearance by the FDA or Appropriate Regulatory Framework
Adoption	Physician Education Campaigns
	Engagement with Medical Specialty Societies and Patient Advocacy Groups
	Incorporation of Technology into Specialty Society Guidelines
	Engagement with Health Technology Assessment (HTA) and Advisory Groups that Provide Treatment Recommendations
Reimbursement	Coverage
	Coding & Payment Assignment
	Payment & Contracting

Response to Finding No. 195

The proposed finding is vague and confusing. It is vague because the term "each factor" is undefined and provided without context. The table itself is vague and confusing because the terms "factor" and "key components" are undefined and provided without context. Respondents have simply copy-pasted a table from Dr. Deverka's report into their findings. It is unclear what specific finding or factual proposition is even being offered. Therefore, this Court should disregard the proposed finding.

1. **Evidence Development**

196. Public payors—such as Medicare and Medicaid—and private payors consider numerous factors when deciding whether to cover a new test, including evidence of effectiveness, safety, the product's indication, the product's appropriate use population, and cost. In particular, the following types of evidence are considered:

Response to Finding No. 196

The proposed finding is unsupported because no evidence is cited for the statement that public and private payors consider numerous factors when deciding whether to cover a new test, including evidence of effectiveness, safety, the product's indication, the product's appropriate use population, and cost. The Court should disregard the proposed finding.

Additionally, the proposed finding is vague because the terms "product indication" and "appropriate use population" are undefined.

196.1 Analytic Validity. How well the test predicts the presence or absence of a particular biomarker. (RX6001 (Deverka Trial Dep. at 33–34); RX3867 (Deverka Expert Report) ¶ 31.)

Response to Finding No. 196.1

The proposed finding is vague and confusing because it is not a complete sentence, and it is unclear what factual statement is being proffered. To the extent that Respondents are offering a definition, this Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Deverka as the only source of evidence supporting the definition of analytic validity. [redacted] This Court should disregard this evidence and the proposed finding.

196.2 Clinical Validity. How well an analyzed biomarker is related to the presence, absence, or risk of a specific disease. (RX6001 (Deverka Trial Dep. at 33–34); RX3867 (Deverka Expert Report) ¶ 31.)

Response to Finding No. 196.2

The proposed finding is vague and confusing because it is not a complete sentence, and it is unclear what factual statement is being proffered. To the extent that Respondents are offering a definition, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Deverka as the only source of evidence supporting the definition of clinical validity. [redacted] This Court should disregard this evidence and the proposed finding.

196.3 Clinical Utility. The ability of a screening or diagnostic test to prevent or ameliorate adverse health outcomes (e.g., mortality, morbidity, or disability) by enabling the clinician to identify and adopt appropriate treatments or to otherwise alter clinical care decisions that lead to improved health outcomes, while also accounting for the harms of testing. (RX6001 (Deverka Trial Dep. at 34); RX3867 (Deverka Expert Report) ¶ 31.)

Response to Finding No. 196.3

The proposed finding is vague and confusing because it is not a complete sentence, and it is unclear what factual statement is being proffered. To the extent that Respondents are offering

a definition, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Deverka as the only source of evidence supporting the definition of clinical utility. [redacted] This Court should disregard this evidence and the proposed finding.

196.4 Health Economic Evidence. The budgetary impact or cost-effectiveness of adopting or covering a new test on a health plan or the health care system at large. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 31.)

Response to Finding No. 196.4

The proposed finding is vague and confusing because it is not a complete sentence, and it is unclear what factual statement is being proffered. To the extent that Respondents are offering a definition, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Deverka as the only source of evidence supporting the definition of health economic evidence. [redacted] This Court should disregard this evidence and the proposed finding.

197. Generating this evidence is a costly and time-intensive endeavor, often requiring extensive clinical trials to get the amount and quality of data to satisfy public and private payors. (RX3867 (Deverka Expert Report) ¶ 31.)

Response to Finding No. 197

The proposed finding is vague, confusing, and speculative. The proposed finding is vague because the terms "generating," "this evidence," "costly," "time-intensive," "often,"

"extensive," "amount and quality of data" and "satisfy" are undefined and provided without context. Generating any evidence requires both cost and time. For support, Respondents cite only to the paid testimony of Dr. Deverka. Indeed, the proposed finding is merely a sentence from Dr. Deverka's report that Respondents have copy-pasted into their own findings. Dr. Deverka lacks foundation. Dr. Deverka testified during her trial deposition that the only expertise she identifies in her report is as a "health services and policy researcher." (RX6001 (Deverka Trial Dep. at 125)). Therefore, this Court should disregard the proposed finding.

2. **Regulatory**

198. Payors will also consider the regulatory status of a new test. Payors may be more apt to cover a test that is perceived to have undergone a more rigorous review process, and therefore may cover an FDA approved test more readily than an LDT, with a FDA-cleared test treated as an intermediate preference between the two. [redacted]; PX7090 (Sood (Guardant) Dep. at 124); PX7077 (Chahine (Helio) Dep. at 41–42); PX7116 (Dolan (Quest) Dep. at 66); RX3867 (Deverka Expert Report) ¶ 36.)

Response to Finding No. 198

Complaint Counsel has no specific response to this proposed finding.

199. Medicare is currently statutorily prohibited from covering most preventive services including cancer screening tests, unless carved out as a legislative exemption, which may be influenced based on regulatory status. (RX3646 (Social Security Act § 1833, 42 U.S.C. § 1395I).) Private payors are not prohibited from covering LDTs, however, payors may prefer to cover a screening test that is FDA approved. (RX3867, (Deverka Expert Report) ¶ 36.)

Response to Finding No. 199

The proposed finding is vague and improper. Respondents' finding is vague because the terms "preventative services," "carved out," "may be influenced," "regulatory states," "cover," and "may prefer" are undefined and ambiguous. Respondents' citation to RX3646 for the first sentence of the finding is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page

number." (Order on Post-Trial Findings at 3). RX1605 is a 48-page document. Respondents fail to provide a citation to a specific page number (or to any specific subsection of the Social Security Act) in contravention of the Court's Order. It is not this Court's job to dig through 48 pages of the Social Security Act to discern what support, if any, is provided for Respondents' claim. The Court should disregard this proposed evidence. Complaint Counsel does not disagree that private payors are not prohibited from paying for LDTs. Although the term "may prefer" is ambiguous, Complaint Counsel does not disagree that [redacted]

[redacted]

3. **Adoption**

200. In addition to public and private payors, a number of other stakeholders influence the availability of novel medical tests and any MCED test developer must attempt to engage these stakeholders to communicate the value of their test, including health technology assessment (HTA) and advisory bodies, patient advocacy groups, and medical specialty societies. (RX3005 (Deloitte); RX3867 (Deverka Expert Report) ¶ 37.)

Response to Finding No. 200

The proposed finding is vague because the terms "stakeholders," "communicate the value," "influence," "engage," "health technology assessment (HTA) and advisory bodies," "patient advocacy groups," and "medical specialty societies" are undefined. Therefore, this Court should disregard the proposed finding.

201. Each of these stakeholders plays an integral role in shaping treatment pathways and innovation in oncology, thereby influencing coverage in addition to utilization of oncology tests and treatments. (RX3867 (Deverka Expert Report) ¶ 37.)

Response to Finding No. 201

The entire proposed finding is vague. The proposed finding is vague because it does not specify who "these stakeholders" refers to, and the terms "integral role," "shaping," "treatment pathways and innovation," and "influencing," are ambiguous. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or

documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite [redacted] This Court should disregard this evidence and the proposed finding.

202. Health Technology Assessment (HTA) and Advisory Bodies. HTAs evaluate the benefits and shortcomings of medical products, including cost, value and expected clinical outcomes, to provide recommendations regarding coverage and adoption of these products. (RX6001 (Deverka Trial Dep. at 43–44); RX3867 (Deverka Expert Report) ¶ 38.)

Response to Finding No. 202

The proposed finding is vague and relies on improper expert opinion. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite [redacted] This Court should disregard this evidence. The proposed finding is vague because, notwithstanding the purported definition, it is unclear what specific organization or organizations are being referred to as HTAs and what specific role (official or otherwise), if any, they are alleged to have in coverage and adoption decisions. Therefore, this Court should disregard the proposed finding.

202.1 Recommendations from HTA bodies may either increase or decrease access to a new test, depending on the final recommendation and indications/populations that HTAs conclude are most appropriate for a new technology. (RX6001 (Deverka Trial Dep. at 43–44); RX3867 (Deverka Expert Report) ¶ 38.)

Response to Finding No. 202.1

The proposed finding is vague because the term "HTA bodies" is undefined; it is unclear what specific organization or organizations are being referred to as "HTA bodies" and what specific role (official or otherwise), if any, they are alleged to have in coverage and adoption decisions. Similarly, the term "may either increase or decrease access" is ambiguous. Therefore, this Court should disregard the proposed finding.

> 202.2 Among the most influential HTA organizations is the USPSTF, which influences coverage and adoption of medical services through a review system that ultimately assigns a letter grade to the reviewed service, indicating positive or negative support. (RX3867 (Deverka Expert Report) ¶ 39.)

Response to Finding No. 202.2

Complaint Counsel does not disagree that USPSTF is a guideline group that assigns letter ratings to products. [redacted] Beyond that, the proposed finding is vague because the term "[a]mong the most influential HTA organizations" is undefined and it is unclear what entities are intended to be included within the definition "HTA organizations." [redacted]

[redacted]

Additionally, the proposed finding is vague because the terms "most influential" and "influences" are ambiguous. With the exception of the specific points noted above with which Complaint Counsel does not disagree, this Court should disregard the proposed finding.

> 202.3 USPSTF recommendations also impact whether a screening test can be covered by Medicare, where Medicare has statutory authority to cover only preventive tests with a USPSTF A or B rating. (RX3646 (Social Security Act § 1833, 42 U.S.C. § 1395I); RX6001 (Deverka Trial Dep. at 50); RX3867 (Deverka Expert Report) ¶ 39.)

Response to Finding No. 202.3

Complaint Counsel does not disagree that USPSTF recommendations can affect Medicare coverage decisions. Complaint Counsel also does not disagree that the Medicare Act allows and provides for Medicare to pay for certain services if they are ranked as an A- of B-rated service by USPSTF.

203. Medical Specialty Societies. Test manufacturers must engage with specialty societies to communicate the clinical validity and utility of a new test to physicians and pathologists. (RX3867 (Deverka Expert Report) ¶ 40.)

Response to Finding No. 203

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, [redacted]; *see* Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on Dr. Deverka's expert

opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Deverka's report, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "specialty societies," clinical validity," and "pathologists" are undefined. Additionally, the term "engage with" is ambiguous and unclear.

> 203.1 Medical specialty societies such as the American Medical Association (AMA), the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO®), and American Clinical Laboratory Association (ACLA), provide a range of services for their members, including providing practice support, participating in relevant lobbying efforts, and considering the role of new technologies in existing care paradigms. (RX3867 (Deverka Expert Report) ¶ 40.)

Response to Finding No. 203.1

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3).

The proposed finding is vague because the term "medical specialty societies" is

undefined and the terms "providing practice support" and "considering the role of new technologies" are ambiguous. Additionally, it is not clear who the members of specialty societies are.

203.2 Specialty societies such as NCCN and ASCO® develop guidelines that provide screening, diagnostic workup and treatment recommendations based on comprehensive literature reviews. (RX6001 (Deverka Trial Dep. at 44–45); RX3867 (Deverka Expert Report) ¶ 40.)

Response to Finding No. 203.2

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because the terms "specialty societies" and "diagnostic workup" are undefined. Additionally, the proposed finding does not specify what literature the specialty society guidelines are based on.

203.3 For instance, NCCN most recently updated its guidelines in 2021 that detail recommended screening paradigms, including frequency and modalities, for lung

cancer and breast cancer, called the "Lung Cancer Screening" and "Breast Cancer Screening and Diagnosis" guidelines, respectively. (RX3867 (Deverka Expert Report) ¶ 40.) Such guidelines heavily influence testing and treatment decisions across U.S. physician practices. (RX3867 (Deverka Expert Report) ¶ 40.)

Response to Finding No. 203.3

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because the opening phrase "for instance" is provided without context. Additionally, the term "heavily influence" is ambiguous and vague.

203.4 Particularly for new technologies such as MCED screening, physicians may be unaware of test indications, appropriate populations for testing, and how to interpret test results. (RX3867 (Deverka Expert Report) ¶ 40.)

Response to Finding No. 203.4

The proposed finding is vague because the terms "test indications," "appropriate

populations", and "interpret" are undefined. Therefore, this Court should disregard the proposed finding.

> 203.5 Without engagement of these specialty societies, new technologies may go unused despite a positive reimbursement environment. (RX3516 (Bevers et al., NCCN Breast Cancer Screening and Diagnosis); RX6001 (Deverka Trial Dep. at 44–45); RX3518 (Wood, et al., NCCN Lung Cancer Screening); RX3867 (Deverka Expert Report) ¶ 40.)

Response to Finding No. 203.5

The proposed finding is improper and vague. Additionally, Respondents' citations to RX3516 and RX3518 are in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3516 and RX3518 are a multi-page documents; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

Moreover, it is unclear how RX3516 and RX3518 support the proposition of this proposed finding of fact. RX3516 and RX3518 are NCCN Breast Cancer and Lung Cancer Screening and Diagnosis Guidelines, respectively. Neither document supports the statement that "without engagement from these specialty societies, new technologies may go unused despite a positive reimbursement environment." These documents are simply guidelines.

The proposed finding is vague because the terms "these specialty societies" and "positive reinforcement environment" are ambiguous and undefined. Additionally, it is not clear who is engaging with these specialty societies, what this engagement looks like, how often and when this engagement might happen, or what the goal of this engagement is. Therefore, this Court should disregard the proposed finding.

204. Patient Advocacy Groups. Patient advocacy groups drive initiatives and promote policy agendas that improve patient outcomes. (RX3867 (Deverka Expert Report) ¶ 42.)

Response to Finding No. 204

The proposed finding is vague because the term "patient advocacy groups" is undefined. The terms "drive initiatives" and "promote policy agendas" are also overly broad and ambiguous. Therefore, this Court should disregard the proposed finding.

> 204.1 Advocacy groups are often focused on the treatment and detection of select disease areas, such as oncology. (RX3867 (Deverka Expert Report) ¶ 42.) An oncology advocacy group generally focuses on the treatment and detection of select tumor types. (RX3867 (Deverka Expert Report) ¶ 42.)

Response to Finding No. 204.1

The proposed finding is vague because the term "advocacy groups" is undefined and the term "generally focuses on" is ambiguous. Therefore, this Court should disregard the proposed finding.

> 204.2 For instance, advocacy groups may drive education regarding the use of MCED screening for select tumor types, including how MCED screening fits into the standard treatment paradigm for that cancer, the risks and rewards of MCED screening for that cancer, and how family history or other risk factors may influence the benefit of MCED screening. (RX6001 (Deverka Trial Dep. at 45–46); RX3867 (Deverka Expert Report) ¶ 42.)

Response to Finding No. 204.2

The proposed finding is vague because the opening phrase "for instance" provided without context, and the term "advocacy groups" is undefined. Therefore, this Court should disregard the proposed finding.

> 204.3 This is particularly important because while MCED tests screen across many cancer types at once, the patient needs, risks, and existing treatment options across cancers differ. (RX3534 (Putcha G., One Size Does Not Fit All); RX6001 (Deverka Trial Dep. at 45–46); RX3867 (Deverka Expert Report) ¶ 42.)

Response to Finding No. 204.3

The proposed finding is vague and confusing and represents improper expert opinion.

The proposed finding is vague and confusing term "this" is undefined and provided without context. The citation to RX3534 is incomplete and fails to properly identify the source. Moreover, RX3534 is a multi-page document; to the extent Respondents purport to cite RX3534 as the source of the proposed finding, they fail to provide a citation to any specific page number or page range. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. Respondents' citation to RX3534 violates the Court's Order and the Court should disregard this proposed evidence. Moreover, this is not a properly constructed finding of fact, but rather a sentence Respondents simply copy-pasted from Dr. Deverka's report. The finding is misleading as to source; it obscures this origin by failing to quote Dr. Deverka and by purporting to cite RX3534 as the primary source of the specific language proposed. To the extent that Respondents cite Dr. Deverka, [redacted] Therefore, this Court should disregard the proposed finding.

4. **Reimbursement**

205. Payor reimbursement is a complex, multi-step effort. Coverage defines the range and extent of services and products for which an insurer will pay. Coding is the language that characterizes services, procedures and products rendered to patients, and insurers rely on that coding to define which products and services will or will not be reimbursed.

Response to Finding No. 205

The proposed finding is unsupported by any evidence and should be disregarded. It is also vague to the extent that the term "complex, multi-step effort" is ambiguous.

206. Payment is the amount and process by which reimbursement is made by an insurer for a covered service and/or technology which may involve development of contracts and associated contracted rates between payor and manufacturer. In addition to each of these components of reimbursement, manufacturers must also secure appropriate regulatory

authorization dependent on the type of product. (RX6001 (Deverka Trial Dep. at 47–48); RX3867 (Deverka Expert Report) ¶ 43.)

Response to Finding No. 206

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because the terms "development of contracts" and "associated contracted rates" are ambiguous and undefined. Additionally, it is not clear what "appropriate regulatory authorization" is or how it might be secured by manufacturers.

a. Medicare and Medicaid

(i) Development of Coverage Determinations

207. Positive Medicare coverage is critical for cancer screening test developers to ensure accessibility of tests among individuals who are most at risk. (RX6001 (Deverka Trial Dep. at 48.) Medicare is generally available for individuals 65 or older as well as certain younger people with disabilities. (RX3742 (Who is Eligible for Medicare?) at 1.) Based on the common age ranges in which new cancer cases are identified, Medicare coverage will be critical

for widespread access to MCED screening. (RX6001 (Deverka Trial Dep. at 48); RX3867 (Deverka Expert Report) ¶ 44.)

Response to Finding No. 207

The proposed finding is vague because the term "positive Medicare coverage" is undefined and the phrase "will be critical" is ambiguous. Additionally, the proposed finding does not identify the "individuals who are most at risk" and does not specify the "common age ranges in which new cancer cases are identified." Therefore, this Court should disregard the proposed finding.

208. SEER data from 2014–2018 indicates that cancer of any site is most frequently diagnosed in individuals aged 65–74, with a median age of 66. (RX3091 (NCI) at 1). The data show that 28.7% of newly diagnosed cancer cases during this time period occurred in individuals aged 65–74, while 24.3% occurred in individuals aged 55–64, aligning with the population for which Galleri is currently recommended (ages 50+). (RX3091 (NCI) at 1; RX6001 (Deverka Trial Dep. at 48); RX3867 (Deverka Expert Report) ¶ 44.)

Response to Finding No. 208

The proposed finding is improper, unsupported, and vague. RX3091, which was pulled from the National Cancer Institute website, provides no support for the proposed finding. RX3091 includes statistics on the risk and prevalence of cancer in the US and specifically tracks the rate of new cases, the death rate, and the 5-year relative survival rate for cancer of any cancer site. However, RX3091 does not include any information on the age ranges of newly diagnosed cancer patients.

[redacted]

[redacted]

The proposed finding is vague because the term "SEER data" is undefined.

209. Medicare's coverage policies are developed in one of two formats: National Coverage Determinations (NCDs) are policies that determine coverage for all Medicare patients nationally, while Local Coverage Determinations (LCDs) are regionally developed policies by Medicare Administrative Contractors (MACs) that specify coverage specific to that MAC's jurisdiction, in the absence of an NCD. (RX3453 (CMS) at 1; RX6001 (Deverka Trial Dep. at 48–49).)

Response to Finding No. 209

The proposed finding is misleading because Respondents fail to identify [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

210. When determining coverage for their Medicare Advantage plans, private payors must cover all services with a positive coverage determination across NCDs, and across LCDs within that plan's region. (RX3867 (Deverka Expert Report) ¶ 45.)

Response to Finding No. 210

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The proposed finding is vague because the term "Medicare Advantage Plans" is undefined.

211. Pertinent to MCED tests, under § 1862(a)(1)(A) of the SSA, Medicare does not cover experimental or investigational items and services, except in cases of "research conducted pursuant to [Agency for Healthcare Research and Quality (AHRQ) authority]". (RX3648 (Social Security Act § 1862 [42 U.S.C. 1395y]).) § 1142(a)(1) indicates that AHRQ has the authority to "support research with respect to the outcomes, effectiveness, and appropriateness of healthcare services." (RX3645 (Social Security Act § 1142 [42 U.S.C. 1320b–12]).)

Response to Finding No. 211

The proposed finding is misleading and vague. Respondents' failure to identify [redacted]

The proposed finding is vague because it does not explain why the quoted sections of Social Security Act are "pertinent to MCED tests." Additionally, the term "Agency for Healthcare Research and Quality (AHRQ) authority" is undefined. Therefore, this Court should disregard the proposed finding.

211.1 In 2006, Medicare released its initial guidance for the Coverage with Evidence Development (CED) program, which outlined scenarios for limited coverage of experimental and investigational products and services relating to clinical studies, under the statutory basis of § 1862(a)(1)(A) and § 1142(a)(1). (RX3454 (CMS) at 1.)

Response to Finding No. 211.1

The proposed finding is misleading and vague. Respondents' failure to identify [redacted]

The proposed finding is vague because the terms "limited coverage" and "experimental and investigational products and services relating to clinical studies" are ambiguous. Therefore, this Court should disregard the proposed finding.

> 211.2 CMS finalized the CED policy in 2006 to generate data on the utilization and impact of the item or service evaluated in an NCD so that CMS can: document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; consider future changes in coverage for the item or service; and generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service. (RX3454 (CMS) at 1–2; RX3867 (Deverka Expert Report) ¶ 46.)

Response to Finding No. 211.2

The proposed finding is vague because the terms "appropriateness of use," "future changes," "clinical information," and "evidence base" are undefined or ambiguous. Therefore, this Court should disregard the proposed finding.

212. CMS's initial 2006 guidance outlined two arms of the CED program: 1) Coverage with Appropriateness Determination (CAD), which refers to coverage conditioned on specific additional data collection, and 2) Coverage with Study Participation (CSP), which refers to coverage conditioned on care being delivered in a setting with a pre-specified data collection process and additional protections in place, such as those present in some research studies.' (RX3454 (CMS) at 1; RX3867 (Deverka Expert Report) ¶ 47.)

Response to Finding No. 212

Complaint Counsel has no specific response to the proposed finding.

213. While CMS has since removed use of these terms, scenarios outlined by the previous terminology remain appropriate uses of CED. Instead of outlining CED options as falling under CAD or CSP, present CED guidance generally details requirements of CED studies to ensure that such studies are considered to be AHRQ-supported. (RX3867 (Deverka Expert Report) ¶ 47, n.73; RX3454 (CMS).)

Response to Finding No. 213

The proposed finding is improper and vague. Respondents' citation to RX3454 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number,

followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3454 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The only other source that Respondents cite for the proposed finding is Dr. Deverka's report. Thus, the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the term "AHRQ-supported" is undefined and the phrase "generally details" is ambiguous.

214. While the CED program offers alternative coverage options for manufacturers without a clear coverage pathway through the standard LCD/NCD process, coverage is limited in scope and contingent on completion of an AHRQ-supported clinical study. As a result, CED-based coverage bears additional data reporting burdens and setting restrictions, while still requiring development of a formal coverage determination. (RX3867 (Deverka Expert Report) ¶ 48.)

Response to Finding No. 214

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]

[redacted]; *see* Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Deverka's report, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "AHRQ-supported clinical study" and "formal coverage determination" are undefined. Additionally, the proposed finding does not specify what "alternative coverage options" exist for manufacturers without a clear coverage pathway through the standard LCD/NCD process, and it does not specify the "additional data reporting burdens and setting restrictions" required for CED-based coverage.

215. While Medicare covers individuals aged 65 and older, private payor or Medicaid coverage must be achieved to ensure coverage for those under 64 years old. (RX6001 (Deverka Trial Dep. at 55–56).)

Response to Finding No. 215

The proposed finding is improper, misleading, unsupported, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted], and Respondents cite only to Dr. Deverka's trial deposition for support, in contravention of this Court's Order. [redacted]; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to

support this proposed finding, either here or [redacted], and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is misleading because Respondents fail to identify [redacted].

The proposed finding is unsupported because [redacted] Furthermore, the cited deposition testimony does not reference Medicare or Medicaid coverage. Dr. Deverka only briefly mentions that individuals starting at age 45 and 50 are mostly covered by private insurers. Finally, the proposed finding is vague because the term "ensure coverage" is ambiguous. For the reasons stated above, this Court should disregard the proposed finding.

216. Because low socioeconomic status is correlated with increased cancer incidence and mortality, it is also critical to provide access to MCED screening for the population likely to be covered by Medicaid. (RX3650 (Singh et al., 2017) at 11.)

Response to Finding No. 216

The proposed finding is misleading, unsupported, and vague. Respondents' failure to identify [redacted]

The proposed finding is unsupported because RX3650 only supports the first half of the proposed finding—the fact that low socioeconomic status is correlated with increased cancer incidence and mortality. RX3650 contains no references to MCED screening or Medicaid, and thus does not support the second half of the proposed finding.

The proposed finding is vague because the terms "is correlated with," "provide access," and "population likely to be covered by Medicaid" are ambiguous. Therefore, this Court should

disregard the proposed finding.

217. While Medicaid programs differ on a state-by-state basis, § 1905 [42 U.S.C. § 1936d] of the Social Security Act (SSA) sets federal minimum coverage requirements that all state Medicaid programs must adhere to. RX3649 (Social Security Act § 1905 [42 U.S.C. § 1396d]); (RX3867 (Deverka Expert Report) at 49.) Other items and services, including oncology tests, are covered on a state-by-state basis, where coverage determinations typically lag behind coverage from Medicare and other private payors. (RX3150 (OLC, Patient Protection and Affordable Care Act); RX3438 (MACPAC, Mandatory and Optional Benefits) at 2–3; (RX3867 (Deverka Expert Report) ¶ 49.)

Response to Finding No. 217

The proposed finding is improper, unsupported, and vague. Respondents' citation to RX3150 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3150 is a 900+ page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

[redacted] RX3438 merely lists screening and preventive services as an optional Medicaid benefit. It does not specify oncology tests and provides no support for the assertion that Medicaid coverage determinations typically lag behind coverage from Medicare and other private payors. [redacted]

[redacted]

The proposed finding is vague because the phrase "typically lag" is ambiguous.

218. Manufacturers seeking Medicaid reimbursement for services that fall outside of the scope of the program's national coverage mandates will therefore have to understand how coverage determinations are made on a state-by-state program level, and communicate the value of their test to payors and state-managed Medicaid programs as appropriate. (RX3867 (Deverka Expert Report) ¶ 50.)

Response to Finding No. 218

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here [redacted], and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the term "as appropriate" is ambiguous.

(ii) Statutory Limitations to Coverage

219. While Medicare coverage is primarily dictated by development of coverage determination policies, coverage is limited by statute and other requirements. (RX6001 (Deverka Trial Dep. at 49–50).) Regulations as set forth by 45 CFR § 156.100 of the ACA require individual and small group market health plans to cover a pre-established list of itemized Essential Health Benefits (EHBs), including preventive and wellness services. (RX3150 (OLC); RX3380 (CMS) at 1.)

Response to Finding No. 219

The proposed finding is improper, misleading, and vague. The first sentence of the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted], and Respondents cite only to Dr. Deverka's trial deposition testimony to support the first sentence, in contravention of this Court's Order. [redacted]; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinions to support this portion of the proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence, either here [redacted], and therefore this Court should disregard the first sentence of Respondents' proposed finding.

The proposed finding is misleading because Respondents' fail to [redacted]. Additionally, Respondents' citation to RX3150 is misleading and in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3150 is a 900+ page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The

Court should disregard this proposed evidence.

The proposed finding is vague because the terms "individual and small group market health plans" and "Essential Health Benefits (EHBs)" are undefined. Therefore, this Court should disregard the proposed finding.

220. As a result, eligible plans are required to cover a number of single-cancer screening tests without cost-sharing, including colorectal cancer screening for adults aged 45–75; lung cancer screening for adults aged 55–80 at high risk for lung cancer due to current or past heavy smoking; breast cancer mammography screenings every 2 years for women over 50; and cervical cancer screenings via pap smear for women aged 21–65. (RX3580 (CMS); RX3581 (HealthCare.gov) at 2–3; RX3867 (Deverka Expert Report) ¶ 51.)

Response to Finding No. 220

The proposed finding is vague. First, the opening phrase "as a result" is provided without context. Second, it is not clear which plans are "eligible" or what these plans are eligible for. Third, the term "cost-sharing" is undefined. Therefore, this Court should disregard the proposed finding.

221. However, due to current statutory restrictions, the Medicare program is restricted from providing coverage to preventive services in the vast majority of situations. RX3150 (OLC, Patient Protection and Affordable Care Act; (RX3867 (Deverka Expert Report) ¶ 52.)

Response to Finding No. 221

The proposed finding is improper and vague. Respondents' citation to RX3150 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3150 is a 900+ page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The only other source that Respondents cite for the proposed finding is Dr. Deverka's

report. Thus, the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "current statutory restrictions," "preventive services," and "the vast majority of situations" are ambiguous.

222. As such, manufacturers of new preventive services, including cancer screening tests and presumably MCED tests, cannot gain Medicare coverage through standard processes. Instead, MCED tests can only gain Medicare coverage through an exception to these statutory provisions, which will require prolonged and cumbersome coverage efforts. (RX6001 (Deverka Trial Dep. at 50–51); [redacted]

Response to Finding No. 222

The proposed finding is vague, confusing, and represents improper expert opinion lacking in foundation. This is not a properly constructed finding of fact, but rather a sentence Respondents simply copy-pasted from Dr. Deverka's report. The very beginning of the proposed finding – "As such" – clearly references material not contained within the finding itself. The text following this introduction is thus confusing and lacks context. The proposed finding is vague because the terms "[a]s such," "preventative services," "standard processes," "exception," "these statutory provisions," and "prolonged and cumbersome" are undefined and provided without context. Additionally, Respondents rely solely on the paid expert testimony of Dr. Deverka to support what appear to be some fact or facts about Medicare coverage, "standard processes," and "statutory provisions." This Court ordered that experts shall not be cited to "support factual

propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Respondents' citation to Dr. Deverka as the only source of evidence contravenes this Court's Order. This Court should disregard this evidence. Finally, Dr. Deverka lacks foundation. Dr. Deverka testified during her trial deposition that the only expertise she identifies in her report is as a "health services and policy researcher. (RX6001 (Deverka Trial Dep. at 125)). Dr. Deverka testified during her trial deposition that she is neither an FDA expert nor a regulatory expert. (RX6001 (Deverka Trial Dep. at 126)). Dr. Deverka has never worked at the FDA, Centers for Medicare and Medicaid Services, or at the United States Preventive Services Task Force ("USPSTF"). (RX6001 (Deverka Trial Dep. at 126)). Therefore, this Court should disregard the proposed finding.

223. Ultimately, a manufacturer seeking coverage of a new preventive service, such as an MCED test, has only two available pathways to coverage:

Response to Finding No. 223

The proposed finding is unsupported by any evidence and should be disregarded. It is also vague because it does not specify the "only two available pathways to coverage" for a manufacturer seeking coverage of a new preventative service.

224. USPSTF Review with NCD Development. This pathway requires that a test manufacturer seek development of a USPSTF evidence report reviewing the product, followed by development of an NCD from Medicare. Developing a USPSTF evidence report requires an initial topic selection, work plan development, development of a draft recommendation statement, an associated vote, and eventually development and release of a final report—all of which can take significant time. (RX3720 (USPSTF); [redacted]

Response to Finding No. 224

[redacted]

[redacted]

224.1 During the initial topic selection stage, USPSTF reviews nominated topics by considering each topic's public health importance and potential for impact (i.e. controversy, timeliness), with an intent to balance USPSTF's review portfolio across populations, types of services and disease types. USPSTF selects and prioritizes topics for review, and is not required to review all nominated topics. (RX3720 (USPSTF); [redacted]

Response to Finding No. 224.1

[redacted]

[redacted]

224.2 Next, USPSTF indicates that expected timelines from workplan development to draft recommendation vote is 9–15 months, and then an additional 9 months is typically required between the vote to final recommendation release. (RX3720 (USPSTF).)

Response to Finding No. 224.2

The proposed finding is improper, misleading, and vague. Respondents' citation to RX3720 is in contravention of this Court's Order regarding post-trial findings. This Court

ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3720 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

Respondents' failure to identify [redacted], in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "expected timelines" and "typically required" are ambiguous.

> 224.3 As such, manufacturers with screening tests who seek Medicare coverage through this pathway should not expect approval for at least 1.5 years from the time they apply, followed by development of an NCD for coverage to be established. (RX3720 (USPSTF).) In practice, the USPSTF pathway often takes far longer because of the time it requires up front during the topic selection stage. (RX6001 (Deverka Trial Dep. at 50–51.)

Response to Finding No. 224.3

The proposed finding is improper, misleading, and vague. Respondents' citation to RX3720 is in contravention of this Court's Order regarding post-trial findings. This Court

ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3720 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order.

The only other source that Respondents cite for the proposed finding is Dr. Deverka's trial deposition testimony. Thus, the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted] in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

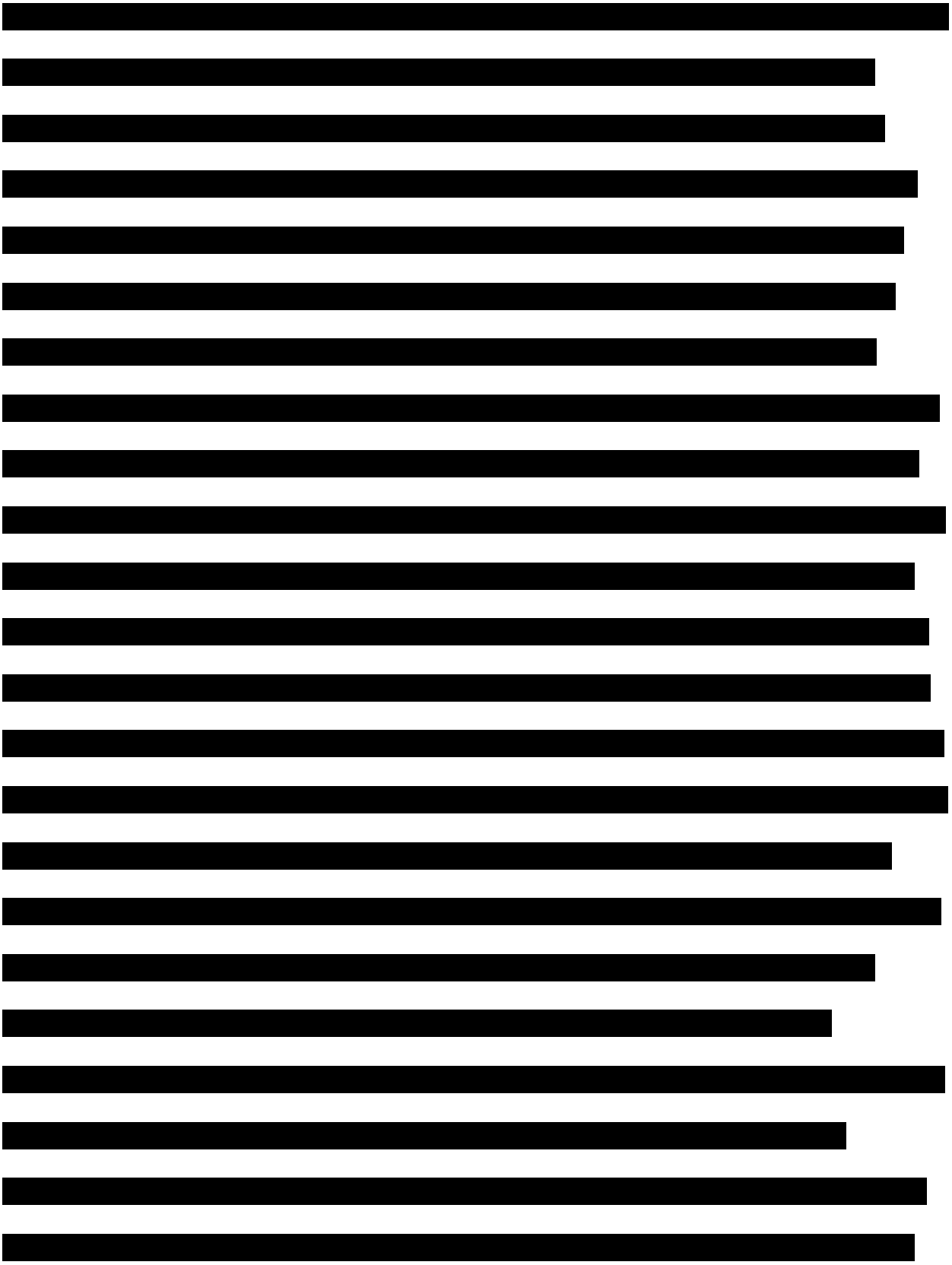
The proposed finding is misleading because Respondents' [redacted]

The proposed finding is vague because the terms "this pathway" and "far longer" are ambiguous. For the reasons stated above, this Court should disregard the proposed finding.

224.4 According to a former USPSTF liaison, it will likely take 5–6 years for the USPSTF to evaluate a novel technology such as MCED tests. (RX3720 (USPSTF); RX1912 (Liquid Biopsy GLG) at 2); [redacted]

Response to Finding No. 224.4

[redacted]



[redacted]

225. Amendment of SSA with LCD/NCD Development. Manufacturers of the MCED test supports passage of Congressional legislation that provides Medicare authorization to cover the test based on a newly developed benefit category. (RX6001 (Deverka Trial Dep. at 49–50, 52); [redacted]

Response to Finding No. 225

[redacted]

225.1 Only a limited number of other preventive services, such as pap smears, mammography, and colon and prostate cancer screening, have successfully used this option. (RX3050 (Balanced Budget Act of 1997 § 4101–04).)

Response to Finding No. 225.1

[redacted]

225.2 Further, coverage for these preventive services is limited to the definition of the service used in the added benefit category. Manufacturers interested in using this pathway to gain coverage would require approval of a bill that amends § 1861 and § 1862 of the SSA, followed by development of a Medicare LCD or NCD.' (RX3647 (Social Security Act § 1861 [42 U.S.C. 1395x] at Part E- Miscellaneous Provisions); RX3648 (Social Security Act § 1862 [42 U.S.C. 1395y] at Exclusions from Coverage and Medicare as a Secondary Payor); [redacted]

Response to Finding No. 225.2

[redacted]

225.3 One such bill, the Multi-Cancer Early Detection Screening Coverage Act (H.R. 1946), was re-introduced by Representative Terri Sewell (D-AL) on March 16, 2021 following its initial introduction as H.R. 8845 during the 116th Congressional session in 2020.' (PX0095 (H.R. 8845); RX3602 (H.R. 1946); [redacted]

Response to Finding No. 225.3

[redacted]

225.4 The bill would add MCED tests as a Medicare benefit category, where a MCED test is defined as an FDA approved/cleared test for early detection across many

cancer types, that is either of the following: 1) A genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids, OR 2) Such other equivalent tests (which are based on urine or other sample of biological material) as the HHS Secretary deems appropriate. [redacted]

Response to Finding No. 225.4

[redacted]

225.5 H.R. 1946 presents several challenges for MCED test manufacturers. First, manufacturers may expend resources in advocating for a bill that may ultimately lose traction and fail to become law, as seen with the bill's predecessor, H.R. 8845.

Response to Finding No. 225.5

The proposed finding is unsupported by any evidence and should be disregarded. It is also vague because the term "expend resources" is ambiguous.

225.6 Second, assuming the bill is passed, manufacturers will be required to achieve FDA approval or clearance to qualify as a product under the new benefit category. (RX6001 (Deverka Trial Dep. at 49–50); RX6001 (Deverka Trial Dep. at 52; [redacted]

Response to Finding No. 225.6

[redacted]

(iii) Alternative Coverage/Regulatory Pathways

226. CMS has developed several alternative streamlined coverage and reimbursement pathways, although each presents its own set of challenges. Such programs include Parallel Review Pilot Program, which is not currently available to MCED tests, and the recently established Medicare Coverage for Innovative Technologies (MCIT) Pathway, for which the

status is unclear and implementation has been delayed until at least December 2021. (RX6001 (Deverka Trial Dep. at 53–55); RX3867 (Deverka Expert Report) ¶ 55.)

Response to Finding No. 226

[redacted]

227. The Parallel Review Pilot Program. The Parallel Review Pilot Program ("Parallel Review") was established in October 2011 and permanently extended in 2016 to create a mechanism for the FDA and CMS to simultaneously review clinical data, decreasing the time between FDA approval and CMS NCD development. (RX3556 (FDA) at 3; RX3867 (Deverka Expert Report) ¶ 56.)

Response to Finding No. 227

Complaint Counsel has no specific response to the proposed finding.

227.1 Since the program's inception, only two tests, Foundation One CDx and Cologuard, have successfully navigated Parallel Review, despite 26 applications and over 60 inquiries. (RX3052 (RAPS) at 1–2; RX3867 (Deverka Expert Report) ¶ 56.) If a test receives a positive coverage determination via the Parallel Review process, private payors must cover the test for their Medicare Advantage population, but do not need to cover the test for their non-Medicare Advantage beneficiaries. (RX3138 (Podemska-Mikluch, 2018) at 1; RX3867 (Deverka Expert Report) ¶ 56.)

Response to Finding No. 227.1

[redacted]

227.2 As a result of statutory restrictions preventing Medicare from covering preventive services, Parallel Review will not be an option for a MCED test like Galleri unless there is legislative action to add MCED tests as a Medicare benefit category, or alternatively, if the test first receives a grade of A or B following successful USPSTF review. (RX3646 (Social Security Act § 1833 [42 U.S.C. 1395I]); RX6001 (Deverka Trial Dep. at 53–54); RX3867 (Deverka Expert Report) ¶ 57.)

Response to Finding No. 227.2

[redacted]

[redacted]

228. The MCIT Pathway. The Medicare Coverage of Innovative Technology (MCIT) Pathway is a new option that may become effective at the end of 2021, although it is unlikely that CMS will allow the rule to become finalized without additional revision given that CMS has delayed implementation of MCIT twice in 2021.

Response to Finding No. 228

The proposed finding is unsupported by any evidence and should be disregarded. The proposed finding is also vague. The term "Medicare Coverage of Innovative Technology (MCIT) Pathway" is undefined and the terms "new option," "the rule," and "additional revision" are ambiguous. The proposed finding does not specify or explain what the MCIT Pathway is an option for, what rule might become finalized, and what additional revision would allow the rule to become finalized. Therefore, this Court should disregard the proposed finding.

228.1 It was initially proposed in 42 CFR Part 405 in August 2020, but was later delayed as a result of a regulatory freeze implemented by the Biden administration on January 20, 2021. (RX3228 (CMS); RX6001 (Deverka Trial Dep. at 54–55); RX3867 (Deverka Expert Report) ¶ 58.)

Response to Finding No. 228.1

The proposed finding is improper and vague. Respondents' citation to RX3228 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3228 is a multi-page document; Respondents fail to provide citations to any specific page number or page range in contravention of the Court's Order. The Court

should disregard this proposed evidence.

The only other sources that Respondents cite for the proposed finding is Dr. Deverka's report and her trial deposition testimony. Thus, the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted] in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the opening word "it" is ambiguous. Respondents do not specify what was initially proposed in 42 CFR Part 405 in August 2020.

> 228.2 While MCIT might offer an accelerated Medicare coverage pathway for certain innovative products, the pathway is limited to FDA-approved or cleared devices and offers only a temporary coverage window of four years, after which a qualifying device loses coverage if not granted coverage via LCD or NCD. (RX3228 (CMS); RX6001 (Deverka Trial Dep. at 54–55); RX3867 (Deverka Expert Report) ¶ 59.)

Response to Finding No. 228.2

The proposed finding is improper and vague. Respondents' citation to RX3228 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3228 is a multi-page document; Respondents fail to provide citations to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The only other sources that Respondents cite for the proposed finding is [redacted]. Thus, the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on [redacted] to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the term "certain innovative products" is ambiguous.

5. **Private Payors**

229. Private payors use a robust evidentiary framework when considering coverage for diagnostic tests, including screening tests. (RX6001 (Deverka Trial Dep. at 56); RX3867 (Deverka Expert Report) ¶ 60.) While private payors may consider Medicare coverage policies when determining the coverage provided to their commercial population, payors are only required to implement Medicare coverage policies for their Medicare Advantage populations. (RX3867 (Deverka Expert Report) ¶ 60.)

Response to Finding No. 229

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see*

Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on [redacted], and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the term "Medicare Advantage populations" is undefined and the term "robust evidentiary framework" is ambiguous.

230. In addition to the components of evidence development previously discussed – *i.e.*, analytical validity, clinical validity, clinical utility and health economic evidence – payors consider a range of factors when determining medical necessity, such as regulatory approval, the product's clinical indication (intended test use based on the signs, symptoms and populations for which a product is used), and health economics. (RX3043 (Akhmetov, 2015) at 1; RX3005 (Deloitte) at 8; RX3584 (Chambers et al., 2015) at 1.)

Response to Finding No. 230

The proposed finding is misleading and vague. Respondents' failure to [redacted] The proposed finding is vague because the terms "medical necessity" and "health economics" are ambiguous and undefined. Therefore, this Court should disregard the proposed finding.

231. Although all diagnostics do not require FDA-approval/clearance, private payors may factor regulatory status into coverage decisions. Separately, payors will consider the product's target population and intended indication, where products that are intended for use in broad populations, like oncology screening tests, will be subject to greater scrutiny due to increased budgetary impact. (RX3867 (Deverka Expert Report) ¶ 60.)

Response to Finding No. 231

The proposed finding is improper and vague. The proposed finding is improper because

this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on [redacted], and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "may factor," "greater scrutiny," and "increased budgetary impact" are ambiguous.

232. When considering the budgetary impact of new products and services, payors will often consider only the short-term benefit to health outcomes, which underemphasizes the potential for long-term cost savings that may be afforded by MCED tests. (RX6001 (Deverka Trial Dep. at 56);RX3084 (Dept. of Veterans Affairs) at 1–2; RX3867 (Deverka Expert Report) ¶ 60.)

Response to Finding No. 232

The proposed finding is misleading, improper, and vague. Respondents' citation to RX3084 is misleading because RX3084 merely provides an explanation of budget impact analysis: a short-term economic assessment from the payor's perspective that estimates the financial consequences of adopting a new intervention. RX3084 does not provide support for the claim that payors often *only* consider short-term benefits when considering the budgetary impact of new services. In other words, RX3084 does not rule out the possibility that payors might consider long-term benefits and cost savings.

The only other sources that Respondents cite for the proposed finding are Dr. Deverka's report and trial deposition testimony. Thus, the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted] *see* Order on Post-Trial Findings at 3). Respondents improperly rely on [redacted] to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "often consider" and "may be afforded" are ambiguous.

F. Specific Barriers and Challenges for Commercialization of MCED Tests

233. As discussed above, manufacturers of new MCED tests face a number of unique challenges regarding test reimbursement and widespread adoption, including the requirement for significant time and financial investments. (RX6001 (Deverka Trial Dep. at 62–64); RX3867 (Deverka Expert Report) ¶ 85; Chahine (Helio) Tr. 1125–27; Getty (Guardant) Tr. 2646–50, 2661.)

Response to Finding No. 233

The proposed finding is improper, unreliable, unsupported, vague, and confusing, and it should be disregarded by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). This proposed finding is, in fact, [redacted]; *see* Order on Post-Trial Findings at 3).

And, moreover, [redacted]. The Court should disregard this finding, as it represents Respondents' effort to pass off their expert's opinions as fact.

The proposed finding is unreliable and unsupported. Besides citing to their own expert's opinions, Respondents rely on only two witnesses to support their contention regarding all "manufacturers of new MCED tests"—Mr. Chahine and Mr. Getty. Mr. Chahine is the Chief Medical and Scientific Officer at Helio, and Mr. Getty is Vice President of Commercial, Cancer Screening Core at Guardant. While they can provide relevant information regarding the challenges facing their own companies, Mr. Chahine and Mr. Getty lack foundation to discuss the "unique challenges" facing all "manufacturers of new MCED tests."

For similar reasons, the proposed finding is unsupported by factual evidence. In the trial testimony cited by Respondents, neither Mr. Chahine nor Mr. Getty provide any information regarding the "number of unique challenges" facing their companies "regarding test reimbursement and widespread adoption." Absent this testimony, the only other support Respondents provide is their own expert's report and testimony, which is, again, improper per this Court's Order. As such, this proposed finding is left without any factual support whatsoever.

The proposed finding is vague, insofar as it fails to quantify "a number of," or provide definitions for "widespread adoption" and "significant time." Similarly, the proposed finding is confusing. First, it is unclear what is meant by "manufacturers of new MCED tests." It is unclear what a "new" MCED test would be compared to an "old" MCED test, and how Respondents differentiate between the two. Second, it is unclear what is meant by "unique challenges"—whether the claimed challenges are unique to the manufacturer, unique to the type of test, or unique only to "manufacturers of new MCED tests" versus some other type of MCED

test. Lastly, the proposed finding is misleading insofar as uses "manufacturers of new MCED tests" to differentiate other MCEDs from Grail, as Grail has not achieved reimbursement or widespread adoption. Therefore, this Court should disregard the proposed finding.

> 233.1 Some of these challenges are due to the novel nature of MCED tests such as the detection of multiple cancers simultaneously, navigation of Medicare statutory coverage limitations that currently do not exist for MCED screening, code development and payment assignment processes for a novel product, FDA approval of a multi-cancer screening test, and campaigns for other education and adoption challenges. (RX3867 (Deverka Expert Report) ¶ 85.)

Response to Finding No. 233.1

The proposed finding is improper, confusing, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise [redacted], and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is also confusing and vague. The proposed finding is confusing because it is unclear whether the finding's predicate describes "these challenges" or "the novel nature of MCED tests." Similarly, the proposed finding is vague, as it fails to provide a definition for "these challenges." This Court should disregard the proposed finding because it is

vague and confusing.

234. Illumina's planned acquisition of GRAIL would allow Illumina to provide critical support to address both the unique challenges for early cancer screening as well as the typical challenges that arise for widespread private and public payor coverage. (RX6001 (Deverka Trial Dep. at 62–64); RX3867 (Deverka Expert Report) ¶ 85.)

Response to Finding No. 234

The proposed finding is improper, confusing, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted] *see* Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Deverka's report, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is misleading as it presumes that Illumina is capable of providing "critical support" to Grail in any capacity. The proposed finding is further misleading in that it assumes the "planned acquisition" is necessary to "allow" Illumina to assist Grail.

The proposed finding is confusing, because it is unclear whether only the claimed "typical challenges" relate to "widespread private and public payor coverage," or whether there are "unique" and "typical" challenges for early cancer screening, both of which relate to widespread private and public payor coverage. Lastly, the proposed finding is vague, because it

fails to provide a definition or explanation of the terms "critical support," "unique challenges," "typical challenges," and "widespread private and public payor coverage."

Finally, the proposed finding is against the weight of the evidence, which shows that, [redacted] The proposed finding is also against the weight of the evidence the extent that it is suggesting that [redacted] Therefore, this Court should disregard the proposed finding.

> 234.1 The particularly innovative aspects of a test that can screen for multiple cancers simultaneously and potentially lead to improvements in cancer outcomes are often the same features that make evaluation of these tests complicated for payors. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 86.)

Response to Finding No. 234.1

The proposed finding is improper, confusing, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). And, moreover, [redacted] Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here [redacted]

[redacted], and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is confusing, perhaps because it is also vague. The proposed finding is confusing and vague because Respondents fail to define "particularly innovative aspects," quantify or define "potentially lead to improvements in cancer outcomes," or quantify what is meant by "often."

The proposed finding is also misleading to the extent it suggests that Illumina is able to advance payor adaptation. Conversely, the weight of the evidence shows [redacted]

Therefore, this Court should disregard the proposed finding.

1. **High Evidence Hurdles**

235. The foremost challenge in bringing a MCED test to market will be the high evidence hurdles that a test developer must surmount before payors will consider providing coverage for the test. (RX6001 (Deverka Trial Dep. at 90–91); RX3867 (Deverka Expert Report) ¶ 87.)

Response to Finding No. 235

The proposed finding is improper, misleading, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]; *see* Order on Post-Trial Findings at 3). And, moreover, [redacted]. Further, Respondents' offered Dr. Deverka as "an

expert concerning the evidence requirements to support payer decision-making for new genomics-based technologies." (RX6001 (Deverka Trial Dep. at 25)). Dr. Deverka has no basis to determine what MCED test developers will consider to be the "foremost challenge" in bringing their tests to market. Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here [redacted], and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is misleading, insofar as it presumes that there is one "foremost challenge" that applies to every MCED test in development without citing to any. The proposed finding is vague, because if fails to define "high evidence hurdles." Moreover, this proposed finding is misleading to the extent that it implies that Grail is not well-positioned to provide clinical evidence to support payor adaptation. As the evidence has shown [redacted]. Therefore, this Court should disregard the proposed finding.

236. MCED tests face particularly burdensome hurdles during evidence development stages given the broad nature of their clinical indication and large scale at which screening methods are implemented. (RX3867 (Deverka Expert Report) ¶ 87.)

Response to Finding No. 236

The proposed finding is improper, misleading, and vague. The proposed finding is improper, because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is [redacted]

[redacted]

The proposed finding is also misleading. First, the proposed finding is misleading insofar as it implies that any MCED tests have a "broad . . . clinical indication." No MCED tests have received clinical indications from the FDA. (PX7086 (Cance (ACS) Dep.) at 49, 58). Second, the proposed finding is misleading insofar as it implies that there are any MCED tests implemented at a "large scale." Similarly, the proposed finding is vague. It fails to define what's meant by "particularly burdensome hurdles," "evidence development stages," "broad nature," and "large scale." [redacted] Therefore, this Court should disregard the proposed finding.

> 236.1 Clinical trials for MCED tests must include many patients from a variety of backgrounds and medical histories. [redacted] Aravanis (Illumina) Tr. 1909–10.) These large sample sizes are required to evaluate MCED tests due to the low prevalence of individual cancer types across the general, asymptomatic population and to account for natural patient attrition during these studies. (RX3867 (Deverka Expert Report) ¶ 87.)

Response to Finding No. 236.1

[redacted]

[redacted]

236.2 Further, studies that look to assess the treatment pathway following cancer detection will require follow-up periods of several years. (RX6001 (Deverka Trial Dep. at 90–91); RX3867 (Deverka Expert Report) ¶ 87.)h

Response to Finding No. 236.2

The proposed finding is improper, vague, and confusing. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3).

[redacted]

[redacted]

The proposed finding is also vague, in that it fails to identify which types of "studies" it discusses, to describe what is meant by "assess[ing] the treatment pathway," and quantify "several." Moreover, the proposed finding is confusing; it is unclear whether (i) there will be multiple "follow-up periods," each lasting "several years"; (ii) there will be multiple "follow-up periods" collectively spanning "several years"; or (iii) whether each study will have one "follow-up period" which will last "several years."

[redacted]

237. High evidence hurdles are the norm for screening tests since the target population is individuals without any signs or symptoms of cancer. (RX3583 (Wilson et al., 1968) at 134; RX3608 (Andermann et al., 2008); RX3156 (Dobrow et al., 2018) at 5.)

Response to Finding No. 237

This proposed finding is vague and confusing, insofar as it fails to define the terms "[h]igh evidence hurdles" and "the norm."

238. It is difficult to be certain about predicting the intended use population for the early adoption of Galleri by payors. (RX6001 (Deverka Trial Dep. at 91–92, 94–95); RX3867 (Deverka Expert Report) ¶ 88.)

Response to Finding No. 238

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is also unclear. At the outset, it is unclear whether the FDA, payors, MCED test developers, Grail, or Dr. Deverka herself considers it "difficult to be certain about predicting the intended use population for the early adoption of Grail by payors." It is also confusing to determine what exactly is difficult about being "certain about predicting the intended use population." From the finding, it is unclear if it is difficult to evaluate predictions about the intended use population or if it is difficult to ascertain the intended use population itself. Moreover, the proposed finding is vague, in that Respondents fail to define what is meant by "early adoption" and "difficult."

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

238.1 Payors may prefer to limit test coverage to higher cancer risk populations to increase the diagnostic yield, limit their financial exposure, and minimize the risk of false positive results, patient anxiety and unnecessary, costly, and potentially harmful follow-up diagnostic procedures. (RX3867 (Deverka Expert Report) ¶ 88.)

Response to Finding No. 238.1

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted] The proposed finding is vague, in that it fails to define what is meant by "limit test coverage," "higher cancer risk populations,"

"diagnostic yield," or "financial exposure." And more importantly, the proposed finding is vague in that it merely discusses, without citation, what "[p]ayors may prefer"—a statement so vague as to hardly be factual at all. Therefore, this Court should disregard the proposed finding.

For the foregoing reasons, this Court should disregard Respondents' proposed finding.

> 238.2 Payors may also want to understand the implications of false negatives to address concerns about the possibility of patients foregoing SOC screening, thereby delaying cancer diagnoses and potentially increasing patient morbidity. (RX3867 (Deverka Expert Report) ¶ 88.)

Response to Finding No. 238.2

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is confusing, in that it discusses "address[ing] concerns," but does not identify whose concerns need addressing. Moreover, the proposed finding is vague, in that it fails to define "the implications" and "SOC," and fails to both define and quantify what is meant by "potentially increasing." And further, Respondents' proposed finding, without any citation to

factual evidence, simply discusses what "[p]ayors may . . . want"—a statement so vague as to hardly be factual at all. Therefore, this Court should disregard the proposed finding.

> 238.3 GRAIL will need to invest time and resources to develop this evidence, either based on additional clinical studies or real-world evidence. (RX6001 (Deverka Trial Dep. at 91–92, 94–95); RX3867 (Deverka Expert Report) ¶ 88.)

Response to Finding No. 238.3

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague. Respondents fail to define the term "this evidence" or quantify the term "additional clinical studies."

239. Some payors may want to see prospectively collected evidence of the impact of MCED screening on mortality, which will require large, long-term follow-up studies. (RX3867 (Deverka Expert Report) ¶ 89.) Valid assessment of patient safety data requires the return of results to participants in a prospective study. (RX3867 (Deverka Expert Report) ¶ 89.)

Response to Finding No. 239

The proposed finding is improper because this Court held that experts shall not be cited

to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague, as it fails to define the terms "some payors," "prospectively collected evidence," "large," "long-term," "valid assessment," and "prospective study." And moreover, Respondents' proposed finding, without any citation to valid factual evidence, discusses what "[s]ome payors may want"—a statement so vague as to hardly be factual at all. Therefore, this Court should disregard the proposed finding.

240. To date, GRAIL has only returned results to patients in one study. PATHFINDER is a prospective study that enrolled 6,662 participants from seven clinical

institutions in the U.S. between December 2019 and December 2020. (RX3044 (NIH); RX6001 (Deverka Trial Dep. at 93–94); RX3867 (Deverka Expert Report) ¶ 89.)

Response to Finding No. 240

The proposed finding is improper, unsupported, vague, unclear, misleading, and—in multiple ways—in contravention with this Court's Order regarding post-trial findings, and it should be disregarded by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

Respondents' citation to RX3044 is misleading. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3044 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence. Moreover, this proposed finding is unsupported, as the cited material does not provide any support for Respondents' contention that "Grail has only returned

results to patient in one study."

The first sentence of the proposed finding is unsupported by any citation. This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have failed to provide any citation to support this sentence, and it is unclear whether the citations following the second sentence apply equally, or at all, to the first sentence. Respondents' proposed finding is also unclear, failing to indicate whether the PATHFINDER study is the "one study" referred to in the first, uncited sentence. Lastly, the proposed finding is vague, in that it fails to define the term "clinical institution."

Complaint Counsel objects to the attribution of RX3044 (a report concerning an NIH study, not an NIH document or a document produced by the NIH) to the NIH as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Therefore, this Court should disregard the proposed finding.

241. Participants whose MCED test results indicated presence of cancer underwent diagnostic testing, as determined by their treating physician informed by standard practice guidelines, to reach a diagnostic resolution - either the diagnosis of an invasive cancer (a "true positive") or no cancer (a "false positive"). (RX3867 (Deverka Expert Report) ¶ 89.)

Response to Finding No. 241

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

This finding is also improper, as Dr. Deverka has no basis to opine—even under the guise of a "fact"—about "standard practice guidelines" or "diagnostic resolutions." Respondents' offered Dr. Deverka as "an expert concerning the evidence requirements to support payer decision-making for new genomics-based technologies." (RX6001 (Deverka Trial Dep. at 25). Her opinions contained within the proposed fact regarding standard practice guidelines and diagnostic resolutions clearly fall outside the scope of the "expertise" for which Respondents' present her. Therefore, this Court should disregard the proposed finding.

> 241.1 Out of 6,629 analyzable test results, 1.4% (or 92 individuals) had a cancer signal detected, and 65 individuals had achieved diagnostic resolution as of March 2021. (RX3053 (Beer et al., 2021).)

Response to Finding No. 241.1

The proposed finding is vague, misleading, and in contravention of the Court's Order regarding post-trial findings, and this Court should therefore disregard Respondents' proposed evidence. The proposed finding is vague, in that it fails to define the term "diagnostic resolution." Similarly, the proposed finding is confusing; it does not identify which study, if any, these "analyzable test results" came from.

Respondents' citation to RX3053 is misleading and in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3053 is a

multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence and the proposed finding.

242. While the first prospective study of Galleri is an important initial step to developing the necessary clinical data, additional and larger studies will be required to begin generating the evidence that payors will require. (RX6001 (Deverka Trial Dep. at 93–94); RX3867 (Deverka Expert Report) ¶ 89.)

Response to Finding No. 242

The proposed finding is improper, vague, and misleading. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3).

[redacted]

The proposed finding is vague, as it fails to define the terms "important," "necessary," "additional," and "larger." [redacted]

[redacted]

242.1 The novelty of a MCED screening approach is likely to slow payor evidence reviews given the unprecedented nature of a single test that screens for multiple cancers. [redacted]

Response to Finding No. 242.1

[redacted]

[redacted]

2. Lack of Precedent For Payor Evaluation

243. There is no precedent that payors can rely on for evaluating the clinical validity and utility of MCED tests. (RX6001 (Deverka Trial Dep. at 116–17); RX3867 (Deverka Expert Report) ¶ 90.) MCED tests are a nascent technology and while some companies have announced plans to develop multi-cancer tests in the future, GRAIL's Galleri test is the only MCED test for asymptomatic individuals that is currently available. (PX7105 (Getty (Guardant) Dep. at 23); [redacted]

Response to Finding No. 243

The proposed finding is improper, vague, misleading, and grossly disingenuous, and should be disregarded by the Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The first sentence of Respondents' proposed finding is vague. It fails to identify which type of payor—public or private—the finding discusses, a distinction Respondents' make in other findings. (*See* RPFF ¶ 234). Moreover, Respondents fail to define the terms "clinical validity" and "utility."

[redacted]

244. Given that GRAIL's test has only very recently been introduced, no company currently has, or is close to receiving payor reimbursement for a MCED test, meaning payors would be evaluating and making coverage decisions on MCED tests for the first time. (RX6001 (Deverka Trial Dep. at 116–17); RX3867 (Deverka Expert Report) ¶ 90.)

Response to Finding No. 244

The proposed finding is improper, vague, misleading, and grossly disingenuous, and

should be disregarded by the Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

Moreover, the proposed finding is unsupported. Other than the improper citations to their expert's report and testimony, Respondents cite to no evidence to support this claim. Indeed, although Dr. Deverka opines about the reimbursement status of all MCED test developers, Respondents fail to cite to any testimony or evidence from any MCED test developer, payor, or other source to support this claim.

The proposed finding is vague; it does not define which Grail test it is discussing or provide a definition for "very recently been introduced" or "is close to." Therefore, this Court should disregard the proposed finding.

245. Typical payor questions regarding whether a new test is clinically meaningful (clinical validity) or useful (clinical utility) will need to be defined for MCED screening in the first instance, as there is currently no consensus interpretation of clinical validity or clinical utility for a MCED test. (RX3867 (Deverka Expert Report) ¶ 91.)

Response to Finding No. 245

The proposed finding is improper, vague, misleading, and grossly disingenuous, and should be disregarded by the Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

Moreover, the proposed finding is unsupported. Other than the improper citation to their expert's report, Respondents cite to no evidence to support this claim. Indeed, although Dr. Deverka opines about "typical payor questions" and "consensus interpretation[s]," Respondents fail to cite to any testimony or evidence from any MCED test developer, payor, or other source to support this claim. Therefore, this Court should disregard the proposed finding.

246. One of the major justifications for adopting MCED screening is the notion of "aggregate prevalence" which refers to where universal screening efficiencies are realized by summing the cancer prevalence rates of individual cancers, thereby increasing the cancer detection rate (CDR), the overall number of true positive cancers detected out of the total number of expected cancers in a monitored population. (RX3715 (Ahlquist, Universal Cancer Screening, 2018) at 4; RX3867 (Deverka Expert Report) ¶ 91.)

Response to Finding No. 246

The proposed finding is improper, vague, and should be disregarded by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague, as it fails to define "major justifications," and it is similarly confusing, by failing to identify who is making this "major justification[]." The proposed finding is also vague because it fails to define "universal screening efficiencies."

247. Even when adding across the five currently screened cancers, the CDR is only 16% for breast, colorectal, lung, cervical and prostate cancers combined—suggesting a relatively low percentage of cancers are identified by current screening methods. (RX3670 (Ong, 2021) at 1; RX3867 (Deverka Expert Report) ¶ 91.)

Response to Finding No. 247

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The proposed finding is vague, in that it fails to define "relatively," and does not indicate what the "relatively low percentage" is relevant to.

248. A MCED test could offer further benefits where the test can screen outside of the five currently screening cancers. (RX3867 (Deverka Expert Report) ¶ 91.) Whereas for many less prevalent cancers single-organ population-wide screening could not be recommended due to the rarity of individual cancer types in average risk adults, a single blood-based test that can detect many different cancer types simultaneously could be justified by aggregating tumor-specific prevalence rates and increasing the overall CDR. (RX3715 (Ahlquist, Universal Cancer Screening, 2018) at 4; RX3867 (Deverka Expert Report) ¶ 91.)

Response to Finding No. 248

Both sentences of Respondents' proposed finding are improper and should be disregarded by the Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

249. However, it is unclear whether payors will accept these presumed benefits of MCED screening or if they will continue to review the clinical validity of any new test for each cancer type individually. (RX3867 (Deverka Expert Report) ¶ 91.)

Response to Finding No. 249

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague, failing to define "unclear," "these presumed benefits," and "any new test." The proposed finding is also confusing—in addition to being vague—because the finding contends "it is unclear," but does not indicate to whom "it is unclear" (i.e., whether payors, some other party, or whether Dr. Deverka herself thinks "it is unclear whether payors" will act a certain way). This proposed finding is impermissibly vague and should be disregarded by this Court.

249.1 If payors were to review the clinical validity for individual cancer types, rather than accepting overall MCED test sensitivity and specificity, this would create an additional evidence challenge for test developers. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 91.)

Response to Finding No. 249.1

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

250. Regardless of how payors review MCED benefits and harms, any MCED test developer, including GRAIL, will need to develop extensive evidence to establish clinical utility of a MCED test. (RX3867 (Deverka Expert Report) ¶ 92.) GRAIL will need to go beyond demonstrating multi-cancer detection rates by cancer type and stage to link these intermediate outcomes to the net health outcomes, such as survival rates and quality of life.

Response to Finding No. 250

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The second sentence of Respondent's proposed finding is uncited. This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly provided no citation whatsoever to the evidentiary record, and this Court should therefore disregard this proposed finding.

251. Given the statistical infeasibility of observing significant survival outcome benefits in the near-term, screening outcomes will need to be modeled. (RX3867 (Deverka Expert Report) ¶ 92.) The requisite sample size, duration of follow-up and costs of data collection make these types of studies very expensive with definitive results not available for potentially decades. (RX3867 (Deverka Expert Report) ¶ 92.)

Response to Finding No. 251

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The proposed finding is vague. It fails to define the terms "statistical infeasibility," "significant," "near-term," "requisite sample size," "duration of follow-up," "costs of data collection," "very expensive," and "potentially decades." The finding is confusing, as it's unclear how the claimed inability to collect data could constitute a "statistical infeasibility"—or, indeed, anything statistical at all. Given Respondents' improper use of expert opinion evidence and because the proposed language is vague, the Court should disregard this proposed finding.

> 251.1 While some single cancer screening models have been used by groups such as CMS to make decisions about covering new tests (e.g., Cologuard for colorectal cancer), there has never been a multi-cancer screening model that has been both peer-reviewed and applied in payor decision-making. (RX3867 (Deverka Expert Report) ¶ 92.)

Response to Finding No. 251.1

The proposed finding is improper, unsupported, vague, and should be disregarded by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

Absent expert opinion evidence, the proposed finding is unsupported. Indeed, Respondents' proposed finding makes a claim concerning Cologuard, and yet Respondents offer no evidence from Exact Sciences--the company producing Cologuard. Numerous Exact employees sat for depositions and offered testimony at trial, and Exact produced countless documents into the record. Nonetheless, Respondents opted instead to rely on their paid expert's unsubstantiated opinions to support this factual proposition.

The proposed finding is vague because it fails to define or quantify the terms "some," "groups such as CMS," "CMS," "new tests," "payor," and "applied in payor decision making." Moreover, Respondents fail to indicate whether the "payors" making decision in this context are public or private payors.

> 251.2 Further complicating these models is that each specific cancer included in the model will have different detection rates as well as diagnostic and treatment paths. (RX3727 (Berger et al., 2016) at 2–3; RX3867 (Deverka Expert Report) ¶ 92.)

Response to Finding No. 251.2

The proposed finding is improper, vague, and should be disregarded but this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague, in that it fails to define "these models" and "diagnostic

and treatment paths."

252. More work will need to be done to account for modeling issues such as tumor sojourn times (the total time a cancer would exist in a particular stage if left undetected by screening), and estimating lifetime survival benefits given competing risks of death in a multi-cancer context. (RX3178 (Hubbell et al., 2020) at 4–7; RX3149 (van den Broek et al., 2017) at 12–13; RX3867 (Deverka Expert Report) ¶ 92.)

Response to Finding No. 252

The proposed finding is improper, vague, and should be disregarded but this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because it fails to define "[m]ore work," "account for modeling issues," "lifetime survival benefits," and "competing risks of death." Similarly, the proposed finding is vague and confusing, as it claims "[m]ore work will need to be done," but does not indicate who "need[s]" to perform "[m]ore work."

253. Models that can account for up to 50 cancer types while also following modeling best practices will be extremely complicated, difficult to communicate to payors, and difficult for payors to understand. (RX3178 (Hubbell et al., 2020) at 7; RX3149 (van den Broek et al., 2017) at 12–13.) There will also need to be extensive provider and patient education regarding how to interpret and use Galleri test results in order to create the opportunity to meaningfully measure clinical utility. (RX6001 (Deverka Trial Dep. at 42–43); RX3867 (Deverka Expert Report) ¶ 92.)

Response to Finding No. 253

The proposed finding is improper, vague, misleading, and should be disregarded but this

Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

Moreover, to the extent Respondents' proposed finding implies that Grail's Galleri test is capable of detecting 50 cancers, the proposed finding is incomplete and misleading. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or for that matter, eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted]

[redacted] Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population. CCGA did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). The authors of the CCGA-3 substudy – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of Grail's CCGA-2 study also provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). [redacted]

[redacted]

The first sentence of Respondents' proposed finding is unsupported. Respondents' claim that certain models "will be extremely complicated, difficult to communicate to payors, and difficult for payors to understand." They provide two citations. The first, to RX3178, is a study purporting to model exactly what Respondents claim is "extremely complicated, difficult to communicate to payors, and difficult for payors to understand." Moreover, RX3178 says nothing about whether such models will be "difficult to communicate to payors" or "difficult for payors to understand." The second source—RX3149—concerns a model evaluating breast cancer screening and has nothing to do with modeling for multiple cancers or whether such a model would be difficult "to communicate to payors" or "for payors to understand." Neither of these sources supports Respondents' proposed finding, leaving it as an unsupported quotation from Dr. Deverka's expert report. The Court should therefore reject this proposed finding.

Respondents' proposed finding is vague. It fails to define "modeling best practices," "extremely complicated," "difficult to communicate to payors," "difficult for payors to understand," "extensive," and "meaningfully measure."

3. Single Cancer vs. Multi-Cancer Screening

254. Currently, all covered screening paradigms involve testing for a single cancer. To obtain coverage for any new single-cancer screening test requires significant evidence, including studies comparing the benefits and risks of the new test to either *no screening* for cancers without current guideline-based testing options, or to the current *standard of care (SOC)* for that particular cancer. (RX3867 (Deverka Expert Report) ¶ 93.)

Response to Finding No. 254

The proposed finding is improper, vague, misleading, and should be disregarded by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because the term "standard of care" is undefined. Additionally, the terms "significant evidence" and "current guideline-based testing options" are ambiguous. Respondents do not specify what constitutes "significant evidence" or what guidelines the testing options are based on.

> 254.1 This presents a challenge for MCED tests both because a MCED test may screen for cancers for which there is no current standard of care (*e.g.*, pancreatic cancer) and because there is no current screening paradigm for screening for multiple cancers in a single test. (RX3867 (Deverka Expert Report) ¶ 93.)

Response to Finding No. 254.1

The proposed finding is improper, vague, misleading, and should be disregarded by this Court. The proposed finding is improper because this Court held that experts shall not be cited

to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because the first word—"[t]his"—is ambiguous. It is unclear what "[t]his" refers to, or what presents a challenge for MCED tests. Additionally, the terms "standard of care" and "screening paradigm" are undefined.

255. For currently screened cancers, the harms of testing are typically well known. For example, screening for lung cancer using low-dose computed tomography carries known biopsy risks to evaluate suspicious nodules. (RX3567 (Wiener et al., 2011) at 8; RX3867 (Deverka Expert Report) ¶ 94.)

Response to Finding No. 255

The proposed finding is vague, improper, and should be disregarded by this Court. The proposed finding is vague because the terms "tomography" and "nodules" are undefined. Additionally, the terms "typically well known" and "known biopsy risks" are ambiguous.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

255.1 In contrast, while there are clear advantages to MCED screening tests (*e.g.*, ease of use given simple blood draw potentially leading to improved screening compliance) the benefits and harms of MCED tests are largely unknown at this time and will likely differ by tumor site depending on the different types of low-risk and high-risk follow-up diagnostic procedures and the unknown effects of MCED screening on compliance with SOC screening. (RX3428 (Underwood et al., 2019) at 3; RX3867 (Deverka Expert Report) ¶ 94.)

Response to Finding No. 255.1

The proposed finding is vague, improper, misleading, and should be disregarded by this Court. The proposed finding is vague because the opening phrase "in contrast" is ambiguous. It is unclear what the proposed finding is being contrasted to. Further, Respondents fail to define the terms "clear advantages," "largely unknown," "will likely differ," and "the different types of low-risk and high-risk follow-up diagnostic procedures."

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

255.2 Achieving payor coverage for a MCED test based on robust evidence will be both difficult and time-consuming for any company working in the cancer screening space because of these challenges. (RX6001 (Deverka Trial Dep. at 112–13); RX3867 (Deverka Expert Report) ¶ 94.)

Response to Finding No. 255.2

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague. It fails to define the terms "payor coverage," "robust

evidence," "difficult," "time-consuming," and "these challenges." The proposed finding is also unsupported, as it fails to provide any basis other than Respondents' expert's opinion to discuss whether "any company" developing an MCED test will find something "difficult and time-consuming." Respondents' cite to no evidence from those MCED test developers, despite numerous such companies and their representatives providing testimony in depositions and at trial, and providing large abouts of documentary evidence. And, further, such a contention is outside the scope of Dr. Deverka's expertise. Respondents' offered Dr. Deverka as "an expert concerning the evidence requirements to support payer decision-making for new genomics-based technologies." (RX6001 (Deverka Trial Dep. at 25). Dr. Deverka has no basis to opine regarding whether something will be "difficult [or] time-consuming for any company working in the cancer screening space," nor has she been offered to provide such opinions.

256. Studies designed to accurately characterize the benefits and harms of numerous cancers (up to 50 for Galleri) would need to be very large given the low prevalence of asymptomatic cancer in a screen-eligible population (and potential for patient attrition) and unknown harms of screening for cancers that currently do not have a SOC screening modality. (RX3867 (Deverka Expert Report) ¶ 95.)

Response to Finding No. 256

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The proposed finding is incomplete and misleading. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or for that matter, eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted] The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.,* CCFF ¶ 6233). [redacted] Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

CCGA did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). The authors of the CCGA-3 substudy – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of Grail's CCGA-2 study also provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. [redacted]

The proposed finding is also vague, as it fails to define "accurately characterize," "benefits and harms," "numerous cancers," "very large," and "unknown harms."

257. The overall benefit/risk balance for MCED test screening tests as compared to single cancer screening tests will also likely be based on a much larger number of variables derived from multiple tumor types (up to 50 different cancer types in the case of Galleri). (RX3867 (Deverka Expert Report) ¶ 95.)

Response to Finding No. 257

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is incomplete and misleading. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or for that matter, eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted]

[redacted] The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.,* CCFF ¶ 6233). [redacted] Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population. CCGA did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). The authors of the CCGA-3 substudy – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of Grail's CCGA-2 study also provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that

Galleri can provide early detection of 50+ cancers in an asymptomatic population. [redacted]

The proposed finding is vague. It fails to define the terms "overall benefit/risk balance," "will also likely be based," "much larger number of variables," and "derived from multiple tumor types."

> 257.1 For example, MCED tests have shown varying test sensitivity and specificity that differs by cancer site and by cancer stage because these test performance characteristics depend on tumor size, location and cfDNA shedding rates. (RX3427 (Ignatiadis et al., 2021); RX3867 (Deverka Expert Report) ¶ 95.)

Response to Finding No. 257.1

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

Respondents' proposed finding is also improper, insofar as it relies on Dr. Deverka's expert report, because Respondents' offered Dr. Deverka as "an expert concerning the evidence requirements to support payer decision-making for new genomics-based technologies." (RX6001 (Deverka Trial Dep. at 25). Dr. Deverka has no basis to offer opinions regarding whether "these test performance characteristics depend on tumor size, location and cfDNA shedding rates."

258. In addition, the ability to accurately localize the tissue of origin in a screened positive patient may also vary by cancer. (RX3867 (Deverka Expert Report) ¶ 95.) This complexity of benefit/risk assessment for MCED tests was the topic of discussion in a recent FDA public workshop held by Center for Devices and Radiological Health (CDRH) in 2020, and comparable difficulties will arise in payor decision-making as payors evaluate the clinical utility (net benefits) of new MCED tests. (RX3591 (FDA); RX6001 (Deverka Trial Dep. at 63–64); RX3867 (Deverka Expert Report) ¶ 95.)

Response to Finding No. 258

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague. It fails to define the terms "accurately localize," "complexity of benefit/risk assessment," "recent," "comparable difficulties," and "new MCED tests." The proposed finding is also confusing, in that by failing to define what is meant by "new MCED tests," it is unclear which tests the proposed finding is discussing at all.

4. **Evidence of a Clinical Benefit**

259. On average, patients diagnosed with earlier stage cancers have better rates of survival than patients diagnosed with later stage cancers. (RX3867 (Deverka Expert Report) ¶ 96.)

Response to Finding No. 259

The proposed finding is improper, vague, and should be rejected by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because the terms "on average," "earlier stage cancers," and "later stage cancers" are ambiguous. For instance, it is not clear whether "earlier stage cancers" refers to stages I-II or I-III.

259.1 For example, the 5–year survival rate for patients diagnosed with Stage I breast cancer (cancer localized to the breast) is 99%, whereas it is only 26% for women diagnosed with Stage IV breast cancer (cancer has spread to other parts of the body). (RX3706 (Susan G. Komen) at 2.)

Response to Finding No. 259.1

The proposed finding is vague and should be rejected by this Court. The proposed finding is vague because the opening phrase "for example" is ambiguous. It is not clear what the proposed finding is being provided as an example for. Therefore, this Court should disregard the proposed finding.

260. The major clinical advantage of MCED test is the presumed ability of the test to detect cancers at earlier stages where the prognosis is better and there is a greater likelihood of cure. (RX3588 (Clarke et al., 2020) at 1; RX3867 (Deverka Expert Report) ¶ 96.)

Response to Finding No. 260

The proposed finding is vague, confusing, improper, and should be rejected by this Court. The proposed finding is vague because the terms "earlier stages" and "better" are ambiguous. For instance, it is not clear whether "earlier stages" refers to stages I-II or I-III nor what constitutes a "better prognosis." Moreover, Respondents fail to define the term "major clinical advantage." The proposed finding is also vague and confusing, insofar as it implies that all MCED tests have the same "presumed ability."

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

261. This benefit of a MCED test is referred to as "downstaging" and is the driver for claims about likely improvements in survival and quality of life. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 96.)

Response to Finding No. 261

The proposed finding improper, vague, and should be rejected by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because the term "downstaging" is undefined and it is not clear what "this benefit" refers to. Respondents also fail to define the term "likely improvements." Respondents do not quantify what is meant by "likely."

261.1 This is particularly important for cancers without a current screening modality such as pancreatic or ovarian cancers where the assumption is that a cancer diagnosis obtained through screening is always better than waiting for symptoms to develop. (RX3867 (Deverka Expert Report) ¶ 96.)

Response to Finding No. 261.1

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because it fails to define the phrase "[t]his" and "particularly important." The proposed finding is also confusing because it claims "the assumption is," but does not indicate who is making this assumption or whether this is an assumption made by Dr. Deverka.

262. However, payors may challenge this assumption as related to lead-time bias: the phenomenon where patients' time of death is unchanged, but when measuring survival from the time cancer was screened-detected leads to the erroneous conclusion that survival is improved. (RX3867 (Deverka Expert Report) ¶ 96.)

Response to Finding No. 262

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The proposed finding is vague in that it fails to define "this assumption," "screened-detected," and "erroneous conclusion." The proposed finding is also confusing, verging on nonsensical. It is unclear what is meant, at all, by the phrase "payors may challenge this assumption as related to lead-time bias."

> 262.1 As a result, payors may require additional clinical utility evidence to establish increased survival due to earlier detection. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 96.)

Response to Finding No. 262.1

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The proposed finding is vague. It fails to define "additional," and it is unclear what this proposed finding is "a result" of. Moreover, Respondents' proposed finding discusses what "payors may require," which establishes no factual information whatsoever.

263. With respect to Galleri, specifically, the sensitivity of the assay varies by tumor type and stage. (RX3430 (Liu et al., 2020) at 1; RX3867 (Deverka Expert Report) ¶ 97.) In addition to Galleri, Thrive has published results of a multi-cancer clinical study indicating different levels of sensitivity and specificity. (RX3867 (Deverka Expert Report) ¶ 97, n.193; RX3419 (Lennon et al., 2020).)

Response to Finding No. 263

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is also in contravention of this Court's Order on Post-Trial Findings, as it fails to provide a pin citation in support of the second sentence. This Court

ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3419 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

> 263.1 Given the reliance of the assay on detecting tumor DNA (ctDNA) fragments in the blood—which increase as cancer develops into later stages, it is unsurprising that Galleri has the highest sensitivity for later stage cancers as these represent tumors that have spread regionally or distantly and tend to shed a higher amount of ctDNA. (RX3773 (Klein et al., 2021); RX3867 (Deverka Expert Report) ¶ 97.)

Response to Finding No. 263.1

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is also in contravention of this Court's Order on Post-Trial Findings, as it fails to provide a citation to a page number in support of the second sentence.

This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3773 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. Absent Respondents' citation to improper expert opinion and improper citation to RX3773, the proposed finding is unsupported, and the Court should disregard this proposed evidence.

5. **Additive To Current Screening Tests**

264. Because Galleri is intended to be additive to current standard-of-care screening tests, this approach raises additional questions for payors. (PX7130 (Deverka Dep. at 198); RX3867 (Deverka Expert Report) ¶ 98.)

Response to Finding No. 264

The proposed finding improper, vague, unsupported, and should be disregarded by this Court. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

The proposed finding is vague because it does not specify what "additional questions" are raised for payors. Additionally, it is not clear what "this approach" refers to. Respondents provide no evidence—other than Dr. Deverka's opinion—to support the contention that "Galleri is intended to be additive to current standard-of-care screening tests."

> 264.1 For example, what are the additional clinical benefits of the MCED test for currently screened cancers versus the benefits of the MCED test for cancers that have no currently recommended screening modalities? (RX3867 (Deverka Expert Report) ¶ 98.)

Response to Finding No. 264.1

The proposed finding improper, vague, and should be disregarded by this Court. The proposed finding should be disregarded because Respondents have posed a question, rather than provide a "finding of fact," in direct contravention of this Court's Order (*See* 16 C.F.R. § 3.46; *see generally* Order on Post-Trial Findings). [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

The proposed finding is vague because the opening phrase "for example" is ambiguous. It is unclear what the proposed finding is being provided as an example for. Additionally, the proposed finding does not specify what are the "additional clinical benefits" of the MCED test for currently screened cancers or cancers that have no currently recommended screening modalities.

> 264.2 And what evidence will be required by payors to mitigate the concern that patients who are tested with Galleri and found to have a "no cancer detected" result may have a false sense of reassurance and therefore decreased adherence to routine screening interventions? (RX3867 (Deverka Expert Report) ¶ 98.)

Response to Finding No. 264.2

The proposed finding improper, vague, and should be disregarded by this Court. The proposed finding should be disregarded because Respondents have posed a question, rather than provide a "finding of fact," in direct contravention of this Court's Order (*See* 16 C.F.R. § 3.46; *see generally* Order on Post-Trial Findings). [redacted]

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). [redacted]

[redacted]

264.3 These issues stem from the unique features of MCED tests and are likely to complicate payor evidence reviews as part of coverage decision-making and will require significant educational outreach to payors on the part of MCED test developers. (PX7130 (Deverka Dep. at 198); RX3867 (Deverka Expert Report) ¶ 98.)

Response to Finding No. 264.3

[redacted]

[redacted]

[redacted]

[redacted]

6. **Economic Considerations**

265. With a target population of individuals aged 50 or older with average cancer risk, the size of the eligible population for Galleri and other MCED tests is very large (i.e., most individuals ages 50–79). (RX3867 (Deverka Expert Report) ¶ 99.) [redacted]; Qadan (Illumina) Tr. 4109.)

Response to Finding No. 265

[redacted]

[redacted]

266. Affordability is heavily dependent on the price of Galleri and the testing interval (every 2 years, every year, or more frequently) with significant near-term impact on the per member per month (PMPM) costs of delivering care to an insured population. (RX3867 (Deverka Expert Report) ¶ 100.)

Response to Finding No. 266

[redacted]

267. [redacted]

Response to Finding No. 267

[redacted]

268. While GRAIL and other future MCED test manufacturers may be able to address these economic considerations by emphasizing the value (cost/outcome) of Galleri, in particular long-term value, that argument may not be persuasive to private insurers. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 101.) In this context, value (synonymous with cost-effectiveness) is defined as patient cancer-related health outcomes achieved relative to the costs associated with cancer detection and appropriate clinical follow-up care. (RX3867 (Deverka Expert Report) ¶ 101.)

Response to Finding No. 268

[redacted]

[redacted]

269. Costs are most commonly measured from the health care payor perspective. (RX3867 (Deverka Expert Report) ¶ 101.) Value assessment is inherently comparative, as the goal is to inform the question, "should we pay for this new test *compared to the standard of care?*" (RX3867 (Deverka Expert Report) ¶ 101.)

Response to Finding No. 269

The proposed finding improper, vague, and should be disregarded by this Court. [redacted]

[redacted]

[redacted]

270. If the presumed benefits of MCED screening approaches are realized, this will result in improved survival and quality of life for individuals detected with cancer due to downstaging, which can be measured as cost-effectiveness. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 101.)

Response to Finding No. 270

The proposed finding improper, vague, and should be disregarded by this Court. [redacted]

[redacted]

270.1 For a stable insured population, downstaging is expected to translate into cancer-specific cost-effectiveness because of improved survival and reduced cancer treatment costs or even cures. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 101.)

Response to Finding No. 270.1

The proposed finding improper, vague, and should be rejected by this Court. [redacted]

[redacted]

[redacted]

271. However, even if Galleri is likely to be cost-effective, it will likely not be cost saving. (RX3867 (Deverka Expert Report) ¶ 102.) Whereas a "cost-effective" new technology produces more health benefits at greater cost relative to the current standard of care, a "cost saving" new technology produces the same or more health benefits at a lower cost than the current standard of care. (RX3160 (Goodell et al., 2009) at 2; RX6001 (Deverka Trial Dep. at 115–16); RX3867 (Deverka Expert Report) ¶ 102.)

Response to Finding No. 271

The proposed finding is improper, vague, and should be rejected by this Court. [redacted]

[redacted]

272. Most new technologies introduced into the healthcare marketplace are cost-effective, not cost-saving, with the health benefits accruing over a patient's lifetime. (RX3867 (Deverka Expert Report) ¶ 102.) In the U.S., private payors, however, often have a short time horizon for decision-making (1–3 years) because of high member turnover. (RX3671, (Graves et al., 2017) at 8.)

Response to Finding No. 272

[redacted]

273. These private payors evaluating a new screening test may be less likely to cover a test that is not cost saving despite the potential cost-effectiveness over a longer time period because U.S. private payors are less likely to see the benefits of cost-effective devices during an individual patient's subscription to a particular insurer's plan. (RX3867 (Deverka Expert Report) ¶ 102.)

Response to Finding No. 273

[redacted]

[redacted]

274. Test manufacturers will likely have to expend significant efforts to encourage private payors to incorporate cost-effectiveness data into their evaluation process for MCED tests. (RX3867 (Deverka Expert Report) ¶ 102.)

Response to Finding No. 274

[redacted]

[redacted]

275. In contrast, net health outcome benefits may be more persuasive to Medicare given their lifetime insurance responsibilities to beneficiaries. (RX3867 (Deverka Expert Report) ¶ 102.) In addition, there is evidence that Medicare does consider cost-effectiveness data in their evaluation of preventive services. (RX3459 (Chambers et al., 2014) at 3–4.) Medicare is also prohibited from basing coverage decisions on cost effectiveness data. (RX3458 (Neumann et al., 2012); RX3867 (Deverka Expert Report) ¶ 102, n.199.)

Response to Finding No. 275

The proposed finding is improper, vague, and should be disregarded by this Court. [redacted]

[redacted]

[redacted]

276. Payors will also likely consider the economic costs incurred through the diagnostic follow up required for patients who receive a positive result from a MCED test. (RX3867 (Deverka Expert Report) ¶ 103). Similar to most current single cancer screening tests, while Galleri can presumptively localize the tumor, follow-up diagnostic testing will be required to definitively rule-in cancer. (RX3867 (Deverka Expert Report) ¶ 103.)

Response to Finding No. 276

[redacted]

[redacted]

277. While data from case-control studies indicates Galleri has a very high specificity level (over 99%), until there are robust prospective data about the rates of false positive results with Galleri in average risk populations, payors are likely to be concerned about the potential for downstream clinical and economic harms with MCED screening approaches. (RX3430 (Liu et al., 2020) at 1; RX3867 (Deverka Expert Report) ¶ 103.)

Response to Finding No. 277

[redacted]

[redacted]

277.1 For example, a false positive result with Galleri could lead to unnecessary diagnostic testing and costs, the risk of procedure-related complications, and diminished patient quality of life. (RX3867 (Deverka Expert Report) ¶ 103.)

Response to Finding No. 277.1

[redacted]

278. The PATHFINDER study was GRAIL's first study that returned results of Galleri to patients at both average and increased risk of cancer. (RX3044 (NIH); RX3867 (Deverka Expert Report) ¶ 103.)

Response to Finding No. 278

The proposed finding is improper, unsupported, vague, unclear, misleading, and—in

multiple ways—in contravention with this Court's Order regarding post-trial findings, and it should be disregarded by this Court. [redacted]

Respondents' citation to RX3044 is improper and misleading. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3044 is a multi-page document; Respondents fail to provide a citation to any specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence. Moreover, this proposed finding is unsupported, as the cited material does not provide any support for Respondents' contention that PATHFINDER was "GRAIL's first study that returned results of Galleri to patients at both average and increased risk of cancer."

Complaint Counsel objects to the attribution of RX3044 (a report concerning an NIH

study, not an NIH document or a document produced by the NIH) to the NIH as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3.

279. Payors will likely require further evidence to establish the clinical utility (net benefit) of Galleri and for payors to effectively evaluate the full economic costs of Galleri, including the costs of false positives. (RX6001 (Deverka Trial Dep. at 93–94); RX3867 (Deverka Expert Report) ¶ 103.); Aravanis (Illumina) Tr. 1947.)

Response to Finding No. 279

[redacted]

7. **Equitable Access and the Size of the Eligible Patient Population**

280. The current lack of private and public payor coverage raises significant concerns about equality and access to potentially life-saving tests. (PX7130 (Deverka Dep. at 23–25);

RX3867 (Deverka Expert Report) ¶ 104.) There are numerous disparities in cancer screening adherence and cancer outcomes for minorities and other underserved populations. (RX3662 (Patel et al., 2020) at 1).

Response to Finding No. 280

The proposed finding is improper, vague, and should be rejected by this Court. [redacted]

280.1 Where a new technology could serve to expand access to cancer screening tests, all efforts should be made to avoid exacerbating these disparities and in fact to work towards reducing them in healthcare. (RX3180 (Virnig et al., 2009) at 6–8; RX3867 (Deverka Expert Report) ¶ 104.)

Response to Finding No. 280.1

The proposed finding is vague, confusing, and should be rejected by this Court. [redacted]

[redacted]

281. Factors that are being studied for their relationship to poorer cancer outcomes include insurance status, care-seeking behaviors, income, education, racial differences in healthcare providers, providers' role in delayed diagnosis and Medicaid enrollment. (RX3088 (Zavala et al., 2020) at 2–3; RX3867 (Deverka Expert Report) ¶ 104.)

Response to Finding No. 281

[redacted]

282. The preferred approach is to take advantage of the potential for improved insured member uptake because of reliance on a simple blood draw so that the benefits of MCED screening can be equitably shared. (PX7130 (Deverka Dep. at 23–25); RX3867 (Deverka Expert Report) ¶ 104.)

Response to Finding No. 282

The proposed finding is improper, vague, and should be rejected by this Court. [redacted]

[redacted]

283. Improved cancer outcomes for all persons will not be achieved if MCED screening is introduced under a strictly limited access framework that makes testing narrowly available to only those individuals that can afford these tests by paying out of pocket or who may be members of executive wellness programs or other employer-sponsored wellness initiatives—individuals that on average have lower cancer risk because of their younger age as compared to retirees. (RX3507 (NCI); RX3867 (Deverka Expert Report) ¶ 105.)

Response to Finding No. 283

The proposed finding is improper, misleading, and vague. [redacted]

[redacted] Yet Respondents' citation to RX3507 is misleading. RX3507 only references age and cancer risk. (RX3507 (NCI)). It does not address the availability of MCED tests, frameworks for MCED screening, and executive wellness programs or other employer-sponsored wellness initiatives. (*See* RX3507 (NCI)). Thus, RX3507 does not support the

majority of the proposed finding—only the claim that younger individuals have on average lower cancer risk compares to older individuals. [redacted]

283.1 For example, Galleri is currently available without any insurance coverage at a list price of $949 per test. (RX3253 (GRAIL); RX3867 (Deverka Expert Report) ¶ 105.)

Response to Finding No. 283.1

The proposed finding is improper, unsupported, and vague. [redacted] Respondents' proposed finding is only supported by RX3253. Yet RX3253 does not provide any support for the claim that Galleri

is currently available without any insurance coverage at a list price of $949 per test. RX3253 is an FAQ answering general questions about the Galleri test that does not address cost at all. Absent RX3253 and [redacted] Respondents' proposed finding is unsupported and should be rejected by this Court.

[redacted]

284. Paying out of pocket for an over $900 test that could be potentially life-saving may not be a significant burden for wealthy individuals but it is likely to be far outside the budget of most Americans. (RX3867 (Deverka Expert Report) ¶ 105.) The sooner that Galleri can be adopted and covered by a broad range of payors, the more likely the test could ameliorate long-standing disparities in access and outcomes. (PX7130 (Deverka Dep. at 23–25); RX3867 (Deverka Expert Report) ¶ 105.)

Response to Finding No. 284

[redacted]

[redacted]

8. **Stakeholder Engagement**

285. Given that MCED is a new technology class, payors do not yet have relevant coverage policies. (RX3867 (Deverka Expert Report) ¶ 106). As such, MCED test manufacturers will have to engage with Medicare, Medicaid *and* private payors to adequately demonstrate medical appropriateness based on developed evidence prior to development of new policies. (RX6001 (Deverka Trial Dep. at 31–32); RX3867 (Deverka Expert Report) ¶ 106; Qadan (Illumina) Tr. 4152–53.)

Response to Finding No. 285

The proposed finding is improper, unsupported, and vague. [redacted]

First, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. Second, the proposed finding is unsupported to the extent that it purports to speak for the needs of all MCED developers to engage with Medicare, Medicaid, and private payors while relying solely on the self-serving testimony of an Illumina executive. Dr. Qadan does not have foundation to offer "facts" regarding the needs of all MCED developers.

286. Payors may be apprehensive to provide coverage due to the large indicated population, and therefore substantial budgetary impact, of screening applications without clear evidence of the benefits and harms (clinical utility) of MCED tests. (RX3867 (Deverka Expert Report) ¶ 106).

Response to Finding No. 286

[redacted]

287. Given the challenges and the novelty of MCED screening, test manufacturers will be required to engage with multiple stakeholders to not only demonstrate the utility and effectiveness of their product but to generate interest and understanding about a new testing paradigm. (RX6001 (Deverka Trial Dep. at 31–32); RX3867 (Deverka Expert Report) ¶ 106).

Response to Finding No. 287

[redacted]

[redacted]

288. After development of new codes, corresponding payment assignment, robust evidence development and securement of private and public payor coverage, MCED test manufacturers will still need to overcome a number of educational barriers prior to widespread test adoption, including at the prescribing physician, patient and payor level. (RX6001 (Deverka Trial Dep. at 42–43); [redacted]

Response to Finding No. 288

[redacted]

[redacted]

288.1 The former Vice President of Clinical Business Development at Illumina, John Leite, summarized this particular challenge as: "[O]nce you have a test approved . . . you have to spend money to educate physicians, to educate payors, to educate hospital systems and employers as to why it's important to adopt your tests. And ultimately you're investing to change physician behavior to ultimately change the standard of care. All of these programs are very expensive and require capital." (PX7088 (Leite (Illumina/InterVenn) Dep. at 33).)

Response to Finding No. 288.1

The proposed finding is misleading and vague, and this Court should therefore disregard this proposed evidence. Insofar as it implies that Illumina can assist Grail with the "very expensive [challenge]" described in this finding, such an implication is against the weight of the evidence, [redacted] The proposed finding is vague, in that it fails to define "this particular challenge." Therefore, this Court should disregard the proposed finding.

289. Physicians may be reluctant to adopt new technology, particularly as they may be uncertain how to interpret test results. (PX6097 (Abrams Expert Report) ¶ 32; RX3867 (Deverka Expert Report) ¶ 108.) Galleri offers a sensitivity of ~50% and a specificity of approximately 99%; the specificity rate of ~99% means that a positive test result is a reliable indication of cancer and has a very low risk that healthy individuals will be falsely diagnosed. (RX3279 (Precision Oncology); RX3867 (Deverka Expert Report) ¶ 108.)

Response to Finding No. 289

[redacted]

[redacted]

290. However, the ~50% sensitivity rate (while higher than some current SOC screening tests) means that a negative test result does not guarantee that the patient does not have cancer. (RX3867 (Deverka Expert Report) ¶ 108.) While these rates may be appropriate for Galleri as a screening application, how to interpret and respond to aggregate cancer detection results may not be intuitive to all clinicians. (RX3867 (Deverka Expert Report) ¶ 108.)

Response to Finding No. 290

[redacted]

[redacted]

291. The proper integration of positive MCED test results into the oncology clinical pathway may also differ across tumor types, which could require additional training for physicians depending on their specialty. (RX3534 (Putcha G., One Size Does Not Fit All); PX7130 (Deverka Dep. at 23–25); RX3867 (Deverka Expert Report) ¶ 108.)

Response to Finding No. 291

[redacted]

[redacted]

292. In addition to educational campaigns, GRAIL will need to engage with specialty societies and patient advocacy organizations, and drive inclusion of MCED screening in standard treatment paradigms as outlined in key oncology treatment guidelines, such as those developed by NCCN. (RX6001 (Deverka Trial Dep. at 175–76); RX3867 (Deverka Expert Report) ¶ 109.)

Response to Finding No. 292

[redacted]

[redacted]

293. The totality of these efforts will require substantial resources, time, and funding to ensure broad MCED screening access beyond initial commercial availability. (RX6001 (Deverka Trial Dep. at 175–76); RX3867 (Deverka Expert Report) ¶ 109.)

Response to Finding No. 293

[redacted]

[redacted]

G. Developing a New Cancer Screening Test Capable of Screening for Multiple Cancers Simultaneously is Difficult and Takes Years

294. It is undisputed that developing a cancer screening test, particularly a cancer screening test that simultaneously identifies more than one type of cancer, is a challenging endeavor. [redacted]

Response to Finding No. 294

[redacted]

[redacted]

295. Many years of research and development are needed to generate a blood-based assay that has the appropriate biomarkers needed to have the requisite sensitivity and specificity, not to mention ability to detect a molecular cancer signal of origin. (RX3869 (Cote Expert Report) ¶ 99.)

Response to Finding No. 295

Complaint Counsel objects to the proposed finding because it is vague, it is incomplete and misleading, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not define "appropriate biomarkers" or "requisite sensitivity and specificity."

The proposed finding is incomplete and misleading to the extent that it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote

offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

> 295.1 GRAIL was launched in 2016 within Illumina, and was only able to launch its multi-cancer screening test as an LDT in 2021. (Flatley (Illumina) Tr. 4090; Bishop (GRAIL) Tr. 1322–23.) GRAIL is still years away from seeking FDA approval for its multi-cancer screening test. (Bishop (GRAIL) Tr. 1343; PX7069 (Bishop (GRAIL) IHT at 94).)

Response to Finding No. 295.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, and relies on self-serving testimony.

The proposed finding is vague because it does not define what it means to be "launched … within Illumina."

The proposed finding is misleading because it does not indicate when GRAIL commenced work on an MCED test and because it suggests that all MCED developers will proceed through the same development path and at the pace as GRAIL.

The proposed finding relies solely on the self-serving testimony of Illumina former Executive Chairman and CEO Jay Flatley to report on GRAIL's progress to date, and solely on

the self-serving testimony of GRAIL CEO Hans Bishop to forecast GRAIL's future progress.

Therefore, this Court should disregard the proposed finding

296. Similarly, Thrive was originally founded based on the research from a company called PapGene as well as research from Johns Hopkins University. (PX7101 (Vogelstein (Johns Hopkins University) at 27–28; [redacted] PapGene was started in 2014. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 27–28).)

Response to Finding No. 296

[redacted]

296.1 Thrive has still not launched a commercial version of its cancer screening test, CancerSEEK, seven years later. [redacted]

Response to Finding No. 296.1

[redacted]

[redacted]

296.2 In late 2020, Exact Sciences acquired Thrive. [redacted] PX7101 (Vogelstein (Johns Hopkins University) Dep. at 48–49).)

Response to Finding No. 296.2

[redacted]

296.3

PX7062 (Kollu (GRAIL) IHT at 162);

Response to Finding No. 296.3

297. Other purported MCED test developers are much further behind. For example, Freenome was founded in 2014. (Nolan (Freenome) Tr. 2724; PX7121 (Otte (Freenome) Dep. at 13).)

Response to Finding No. 297

- [redacted]

[redacted]

[redacted]

[redacted]

- [redacted]

[redacted]

298. [redacted]

Response to Finding No. 298

[redacted]

[redacted]

299. [redacted]

Response to Finding No. 299

[redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

300. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Response to Finding No. 300

[redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

[redacted]

301. Even if a company is seeking to add a new cancer type to a cancer screening test, it cannot skip new biomarker discovery, assay development, case-control study, and validation/clinical steps, even if it can reduce sample collection time by relying on previously collected samples for certain steps. [redacted]

Response to Finding No. 301

[redacted]

[redacted]

[redacted]

[redacted]

302. [redacted]

Response to Finding No. 302

[redacted]

- [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1. **Sample Collection and Initial Research**

303. While test developers may pursue these steps in different orders, the initial steps typically involve sample collection, research and biomarker discovery. (Cote Tr. 3783–85; RX3869 (Cote Expert Report) ¶ 104.)

Response to Finding No. 303

Complaint Counsel agrees that MCED test developers do not subscribe to the one-size-fits-all artificial development and commercialization roadmap and timeline that Dr. Cote imposes in his flawed analysis. The proposed finding—which, like numerous of Respondents' other proposed findings, is copied and pasted verbatim from Dr. Cote's report—shows that Dr. Cote admits MCED developers do not all follow the same steps to commercialization in the same order, and that Dr. Cote does not know what path any particular developer will pursue. Moreover, Dr. Cote's admission that these steps may be done in any particular order shows they may also be done in parallel.

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

304. Specifically, a given company needs to collect samples for the new cancer type to perform the new biomarker discovery; even if this company had previously collected samples for one cancer type, these existing samples would not have the new proposed cancer type.
[redacted]

Response to Finding No. 304

[redacted]

[redacted]

[redacted]

304.1 It is critical that samples are collected uniformly according to a sample collection protocol to ensure high quality samples that are comparable. (Aravanis (Illumina) 1899–1900.) "If you were just to mix and match samples collected in different ways from different purposes, you would end up finding [cancer] signals that are just artifacts of those methods. And were you to develop a test in that way . . . likely it wouldn't perform well." (Aravanis (Illumina) 1899–1900.)

Response to Finding No. 304.1

Complaint Counsel objects to the proposed finding because it is vague, self-serving, and inherently speculative.

The proposed finding is vague because it does not explain the context or define what is meant by "samples," "sample collection protocol," "high quality samples," "comparable," or "different purposes."

The proposed finding is self-serving and inherently speculative because for support Respondents cite only to unfounded, self-serving testimony of an Illumina executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture,

this proposed finding of fact should be disregarded.

304.2 [redacted]

Response to Finding No. 304.2

[redacted]

305. During the sample collection period, the test developer may also perform initial technology development and preliminary feasibility studies. [redacted]

Response to Finding No. 305

[redacted]

[redacted]

[redacted]

[redacted]

305.1 For example, as part of the preliminary feasibility assessment, the developer would assess what the development plan would look like, how much it would cost and its probability of success. [redacted]

Response to Finding No. 305.1

[redacted]

[redacted]

[redacted]

[redacted]

306. Biomarker discovery involves efforts by the test developer to identify which biomarkers are the best at predicting that an individual has cancer, and particularly, if that biomarker may be used to distinguish between an individual who has cancer and a healthy subject. [redacted]

Response to Finding No. 306

[redacted]

[redacted]

[redacted]

[redacted]

306.1 Biomarker discovery may involve research to understand what the biological drivers are, and depending on the drivers and the relevant mutations, a given biomarker may be selected. [redacted]

Response to Finding No. 306.1

[redacted]

[redacted]

306.2 While test developers may review the scientific literature, [redacted] given the interest of test developers in developing a test that is unique and differentiated, developers are likely to attempt to identify new biomarkers and loci that are not present in the literature. (RX3869 (Cote Expert Report) ¶ 105.)

Response to Finding No. 306.2

[redacted]

[redacted]

[redacted]

[redacted]

306.3 Once the test developer has discovered relevant biomarkers from the research step, which can take three to five years, the developer moves into assay development or optimization. [redacted]

Response to Finding No. 306.3

[redacted]

[redacted]

[redacted]

[redacted]

306.4 The research stage can often be a substantial investment, costing in the ballpark of $100 to $150 million when accounting for the samples analyzed and the requisite processing. [redacted]

Response to Finding No. 306.4

[redacted]

[redacted]

[redacted]

[redacted]

306.5 According to Dr. Cote, biomarker discovery can take anywhere from 18 months to three years, and in some cases much longer. (Cote Tr. 3785–86.)

Response to Finding No. 306.5

Complaint Counsel objects to the proposed finding because it is misleading, against the weight of the evidence, and because it improperly cites expert testimony, Dr. Cote is not qualified to provide expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading to the extent it suggests that all MCED test developers conduct an identical discrete "biomarker discovery" phase that does not overlap with other test development activities or that all MCED test developers must in general follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline that Dr. Cote invented in his flawed analysis.

[redacted]

[redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source of purported facts in the proposed finding in contravention of this Court's Order.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications

on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

307. Although it is possible that the R&D process may be shortened to add a new cancer type to an existing test because the company has already elected to pursue a mutation or methylation-based approach, the company would still need to pursue new biomarker discovery for the new cancer(s). (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 106.)

Response to Finding No. 307

Complaint Counsel objects to the proposed finding because it is misleading, incorrect, and because it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely taken from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is incorrect because it claims that adding a new cancer type to an

existing cancer screening test requires "new biomarker discovery" and "assay development."

[redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

308. To date, scientists have not discovered any biomarkers that are "pan cancer", and this is not unexpected given what is understood about the biological drivers of cancer. (Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

Response to Finding No. 308

Complaint Counsel objects to the proposed finding because it is vague, misleading, relies only on self-serving testimony, and because it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not explain what "given what is understood about the biological drivers of cancer" means.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is also misleading because, although Dr. Cote cited no support for this statement in his report (RX3869 (Cote Expert Report) ¶ 106), Respondents now fill in that hole by citing self-serving trial testimony from Illumina executive Alex Aravanis as the primary source for this purported fact. To be clear, *first* Dr. Cote wrote a report that ignored market realities in order to craft a narrative that fit Respondents' case, *then* Respondents generated this testimony on demand since they could not find support in the form of reliable evidence such as ordinary course documents and unbiased witness testimony.

This proposed finding is inherently speculative. For support, Respondents cite only to the self-serving testimony of Illumina executive Alex Aravanis and the paid testimony of Dr. Cote that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the witnesses' base conjecture, this proposed finding of fact should be disregarded.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

309. Therefore, even though companies may chance upon one or a few relevant biomarkers for the new cancer type during development of their previous cancer screening test, full biomarker discovery would still be required to identify a panel of biomarkers for the new cancer type(s) to ensure the accuracy, specificity and sensitivity needed for an early cancer

screening test. (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 106; *see also* Aravanis (Illumina) Tr. 1883, 1896–98.)

Response to Finding No. 309

Complaint Counsel objects to the proposed finding because it is confusing, vague, misleading, relies only on self-serving testimony, is incorrect, and because it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is confusing because it begins with "[t]herefore."

The proposed finding is vague because it does not define or explain what is meant by "the accuracy, specificity and sensitivity needed for an early cancer screening test." It is also vague because it does not define "full biomarker discovery."

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is also misleading because, although Dr. Cote cited no support for this statement in his report (RX3869 (Cote Expert Report) ¶ 106), Respondents now fill in that hole by citing self-serving trial testimony from Illumina executive Alex Aravanis as the primary source for this purported fact. To be clear, *first* Dr. Cote wrote a report that ignored market realities in order to craft a narrative that fit Respondents' case, *then* Respondents generated this testimony on demand since they could not find support in the form of reliable evidence such as ordinary course documents and unbiased witness testimony.

This proposed finding is inherently speculative. For support, Respondents cite only to the self-serving testimony of Illumina executive Alex Aravanis and the paid testimony of Dr. Cote that is uncorroborated by any ordinary course documents or analysis. Given the inherent

unreliability of this testimony as well as lack of foundation or explanation for the witnesses' base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is incorrect because it claims that, to add a new cancer type to an existing cancer screening test, "full biomarker discovery would still be required to identify a panel of biomarkers for the new cancer type(s)."

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been

subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

> 309.1 The challenge is multiplied many-fold as the number of cancers under consideration to be screened increases. (RX3869 (Cote Expert Report) ¶ 106; *see also* Aravanis (Illumina) Tr. 1883; 1896–98.)

Response to Finding No. 309.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, relies only on self-serving testimony, is against the weight of the evidence, and because it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not define or explain what is meant by "the challenge."

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is also misleading because, although Dr. Cote cited no support for this statement in his report (RX3869 (Cote Expert Report) ¶ 106), Respondents now fill in that hole by citing self-serving trial testimony from Illumina executive Alex Aravanis as the primary source for this purported fact. To be clear, *first* Dr. Cote wrote a report that ignored market realities in order to craft a narrative that fit Respondents' case, *then* Respondents generated this testimony on demand since they could not find support in the form of reliable evidence such as ordinary course documents and unbiased witness testimony.

The proposed finding is also misleading because Illumina executive Alex Aravanis actually testified that "the time, you know, *might* be similar for each cancer." (Aravanis

(Illumina) Tr. 1896 (emphasis added)).

This proposed finding is inherently speculative. For support, Respondents cite only to the self-serving testimony of Illumina executive Alex Aravanis and the paid testimony of Dr. Cote that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the witnesses' base conjecture, this proposed finding of fact should be disregarded.

The proposed finding claim that "the challenge is multiplied many-fold as the number of cancers under consideration to be screened increases" is against the weight of the evidence. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving this finding unsupported.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility

problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

> 309.2 As Gary Gao of Singlera explained, in ten years, Singlera has only had "enough sample type[s] for five given types of a cancer to validate . . . there are hundreds of different cancer types, and over a ten-year span, you can only collect enough sample for four or five different cancers for validation purpose. So for five different kinds that we can estimate, you know, it may take seven to eight years [to conduct a] prospective trial to have FDA approval. ***For 50 or 100 kinds of cancer, it would take maybe 50 years.*** You know, that's just the reality of it." (Gao (Singlera) Tr. 1883.)

Response to Finding No. 309.2

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence.

The proposed finding is misleading to the extent it suggests that Singlera's PanSEER test would need to detect 50 types cancer in order to compete with Galleri. There is simply no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394 (Appendix B: Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

[redacted]

310. After the test developer is satisfied with the biomarkers selected for the assay, the test developer enters the "development" stage and focuses on optimizing the assay across different metrics, including costs, quality control and other performance characteristics. [redacted]

Response to Finding No. 310

[redacted]

[redacted]

[redacted]

310.1 For example, an assay that is interrogating multiple cancer types, or is analyzing multiple analytes may require more time than the assay development stage for a single cancer assay. [redacted]

Response to Finding No. 310.1

[redacted]

310.2 The development stage can take multiple years and also impose a cost of about $50 to $100 million. (Cote Tr. 3786; [redacted]

Response to Finding No. 310.2

[redacted]

[redacted]

[redacted]

2. **Validation/Clinical Studies**

311. After the test developer has completed the initial research and development steps, to support the marketing and reimbursement of a clinical oncology test as either an LDT or IVD test with FDA approval, oncology test developers must perform clinical studies to validate the efficacy of any clinical oncology test in detecting cancer and to identify the cancers that such tests are intended to detect at an early stage. (PX7086 (Cance (ACS) Dep. at 50); [redacted] 3783–3785, [redacted]

Response to Finding No. 311

[redacted]

[redacted]

[redacted]

312. The studies that are required to validate a diagnostic test, and in particular a multi-cancer screening test, are well-established to be the biggest expense incurred by a clinical test developer in pursuing an early cancer screening test. (Cote Tr. 3793–3794, 3806; PX7118 (Fiedler (FMI) Dep. at 71); [redacted] *see also* PX7090 (Sood (Guardant) Dep. at 26–27); [redacted]

Response to Finding No. 312

[redacted]

[redacted]

312.1 For example, FMI's COO states that clinical trials are "extremely expensive" and "in the tens of thousands per patient" (PX7118 (Fiedler (FMI) Dep. at 71); *see also* [redacted]; *see also* PX7090 (Sood (Guardant) Dep. at 26–27).)

Response to Finding No. 312.1

[redacted]

[redacted]

[redacted]

313. While the requirements for an LDT test are likely to be less stringent than would be required for FDA approval, for an LDT to gain traction with relevant stakeholders, it will have to undergo extensive and rigorous clinical validation. (RX3869 (Cote Expert Report) ¶ 108.)

Response to Finding No. 313

Complaint Counsel objects to the proposed finding because it is vague and misleading, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague regarding what "the requirements for an LDT" refers to. It is also vague because it does not define "relevant stakeholders" or "extensive and rigorous clinical validation."

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing

such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

313.1 [redacted]

Response to Finding No. 313.1

[redacted]

[redacted]

313.2 The American Cancer Society "rel[ies] on published results of those clinical trials to help it establish screening guidelines for MCED tests" (PX7086 (Cance (ACS) Dep. at 36) and "multi-cancer detection tests need more data and validation in order to assist with cancer diagnosis determinations." (PX7086 (Cance (ACS) Dep. at 50); RX3869 (Cote Expert Report) ¶ 108, n.109.)

Response to Finding No. 313.2

[redacted]

[redacted]

[redacted]

314. A test developer may conduct any one of several types of clinical trials in order to launch an LDT test conducted by a CLIA-certified laboratory,. (RX3869 (Cote Expert Report) ¶ 109; *see also* Cote Tr. 3783–85, 3806–07.)

Response to Finding No. 314

Complaint Counsel objects to the proposed finding because it is vague, unsupported, and misleading, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague regarding what is meant by "any one of several types of clinical trials."

The proposed finding is unsupported because the sources cited do not say anything about the type(s) of clinical trials a developer purportedly may conduct "in order to launch an LDT."

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted nearly verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

> 314.1 The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA) passed by Congress in 1988, which established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. (RX3141 (CMS) at 1.)

Response to Finding No. 314.1

Complaint Counsel objects to the proposed finding because it is unsupported and misleading. The source cited (RX3141) does not indicate that CLIA quality standards ensure the "accuracy reliability, and timeliness" of patient test results.

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the proposed finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 109 n. 111). Therefore, this Court should disregard the proposed finding.

314.2 Before a clinical laboratory can apply for state licensure to operate, it must first obtain CLIA certification from the CMS and become a CLIA-certified laboratory. (RX3869 (Cote Expert Report) ¶ 109, n.111; *see also* RX3141 (CMS) at 1; RX3912 (CMS).)

Response to Finding No. 314.2

Complaint Counsel objects to the proposed finding because it is confusing and it improperly cites expert testimony.

The proposed finding is confusing regarding what difference if any there is between "obtain[ing] CLIA certification from the CMS" and "become a CLIA-certified laboratory."

The proposed finding is vague because it does not specify how a clinical laboratory would obtain CLIA certification from the CMS.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

315. Retrospective, case-control study. The simplest of the types of clinical trials is known as a "case-control study." (Cote Tr. 3783–85; PX7086 (Cance (ACS) Dep. at 60–61); RX3869 (Cote Expert Report) ¶ 110.) In the case of the development of a cancer screening test, a study that analyzes specimens (*e.g.*, blood) collected from patients for whom the cancer status

is already known (positive or negative) is "retrospective" because it is backward-looking. (RX3869 (Cote Expert Report) ¶ 110.)

Response to Finding No. 315

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted nearly verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is also misleading to the extent it suggests that all MCED test developers conduct an identical retrospective case-control study that does not overlap with other test development activities or that all MCED test developers must in general follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline that Dr. Cote invented in his flawed analysis.

[redacted]

[redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

> 315.1 A retrospective, case-controlled cohort study uses pre-collected samples from at least two cohorts of individuals: one with samples from patients diagnosed with the target cancer or cancers, and another with samples from healthy donors who have been "matched" by age or other parameters to the cohort of cancer patient. (PX7086 (Cance (ACS) Dep. at 60–61); RX3869 (Cote Expert Report) ¶ 110.)

Response to Finding No. 315.1

Complaint Counsel objects to the proposed finding because it is misleading, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote

offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

315.2 A case-control study may also have a third cohort of samples from patients diagnosed with non-malignant diseases of the same organ or organs for the relevant cancer types. (RX3869 (Cote Expert Report) ¶ 110.)

Response to Finding No. 315.2

Complaint Counsel objects to the proposed finding because it is misleading, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague because it refers to a "third cohort" of samples without specifying what the first two cohorts are.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

> 315.3 There are no specific sample size requirements for such case-control studies. (RX3869 (Cote Expert Report) ¶ 111.) Such studies vary from fewer than 100 samples in each cohort to several thousands of samples in larger studies. (RX3869 (Cote Expert Report) ¶ 111.) Case-control studies range in cost and time from a few months at a cost of less than a million dollars up to a few years at a cost of tens of million dollars. (Cote Tr. 3786; RX3869 (Cote Expert Report) ¶ 111.)

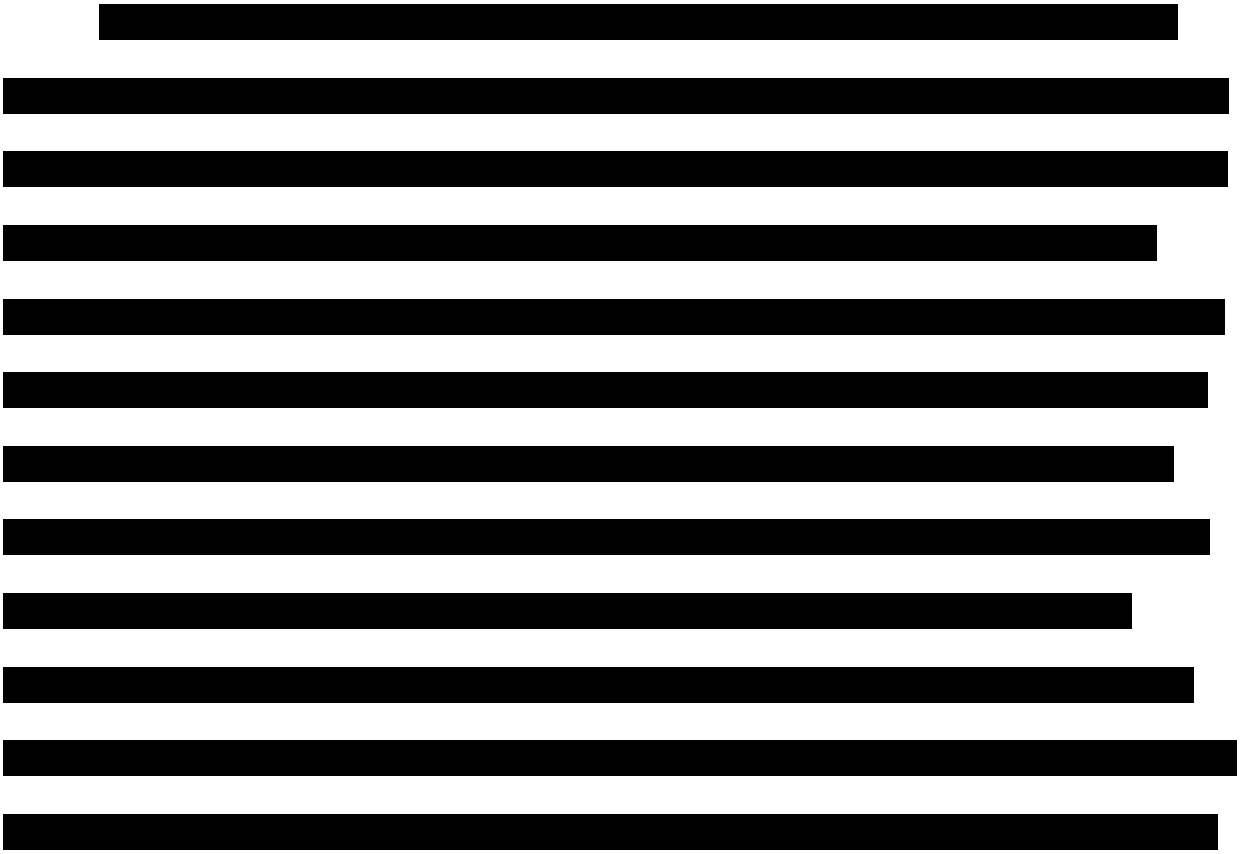
Response to Finding No. 315.3

Complaint Counsel objects to the proposed finding because it is misleading and against

the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is also misleading to the extent it suggests that all MCED test developers conduct an identical retrospective case-control study that does not overlap with other test development activities or that all MCED test developers must in general follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline that Dr. Cote invented in his flawed analysis.



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[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-

known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

315.4 [redacted]

Response to Finding No. 315.4

[redacted]

[redacted]

315.5 A validation study is used to observe, document, and understand variation in the data generated under specific laboratory conditions. (Cote Tr. 3783–85; RX3869 (Cote Expert Report) ¶111, n.115.) Validation helps define the scope or range of conditions under which reliable results may be obtained. (Cote Tr. 3783–85; PX7086 (Cance (ACS) Dep. at 50); [redacted]; RX3869 (Cote Expert Report) ¶111, n.115.)

Response to Finding No. 315.5

[redacted]

[redacted]

[redacted]

316. Prospective, observational study. In contrast to a retrospective study, a study which collects blood from patients who are asymptomatic, and thus have no signs of cancer, and then follows these patients for a period of time to see who develops cancer, is "prospective" or forward-looking. (PX7086 (Cance (ACS) Dep.) at 61–62; Cote Tr. 3783–85.) Participants in a prospective study are enrolled into the study before they develop or are diagnosed with the disease or outcome in question—in the case of cancer screening tests, cancer. (RX3869 (Cote Expert Report) ¶ 112.)

Response to Finding No. 316

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted nearly verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is also misleading to the extent it suggests that all MCED test developers conduct an identical prospective observational study that does not overlap with other test development activities or that all MCED test developers must in general follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline that Dr. Cote invented in his flawed analysis.

[redacted]

[redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

> 316.1 A study is "observational," where the investigator will not act upon study participants, but instead will observe natural relationships between factors and outcomes. (Cote Tr. 3827–28, 3832; RX3869 (Cote Expert Report) ¶ 113.) In an observational study, the physician overseeing the patient will not be informed of any test results at least until after the study is over. (RX3869 (Cote Expert Report) ¶ 113.)

Response to Finding No. 316.1

Complaint Counsel objects to the proposed finding because it is misleading, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

316.2 In contrast to a retrospective case-control study, [redacted] estimated that a prospective observational study of a potential cancer screening test would require samples from at least 5,000 patients over three years of sample acquisition, from both inside [redacted] and from blood banks, at a cost of about $100 million. {([redacted]

Response to Finding No. 316.2

[redacted]

316.3 However, many prospective observational studies for cancer screening tests have been even bigger. (RX3869 (Cote Expert Report) ¶ 114.)

Response to Finding No. 316.3

[redacted]

[redacted]

316.4 Prospective studies for tests that will analyze multiple cancer types simultaneously are likely to require more samples and more funding correspondingly. (Cote Tr. 3806; RX3869 (Cote Expert Report) ¶ 114.)

Response to Finding No. 316.4

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to provide opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague because it does not explain the meaning of "more samples and more funding correspondingly."

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is also misleading to the extent it suggests that MCED test developers are in any way behind or not making progress on developing their MCED tests.

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported fact in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his

expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

317. Prospective, interventional study. A study is "interventional" where the investigator intercedes as part of the study design. (RX3869 (Cote Expert Report) ¶ 115.) In other words, upon a positive finding in a cancer screening study, the physician overseeing the patient will be informed, and is likely to order follow-up tests to rule in or out cancer, and then corresponding treatments if the patient is diagnosed with cancer. (RX3869 (Cote Expert Report) ¶ 115.) The cost of prospective interventional studies is higher than the cost of a prospective observational study. [redacted] 3783–85, 3793–94, [redacted]; RX3869 (Cote Expert Report) ¶ 115.)

Response to Finding No. 317

[redacted]

[redacted]

- [redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

317.1 A study may be called a "longitudinal" study where subjects are followed over time with continuous or repeated monitoring of risk factors or health outcomes, or both. (Gao (Singlera) Tr. 2877–78; RX3869 (Cote Expert Report) ¶ 119, n.123).

Response to Finding No. 317.1

The proposed finding is vague because the terms "over time," "risk factors," and "health

outcomes" are ambiguous. Therefore, this Court should disregard the proposed finding.

> 317.2 A "registrational" trial is where the study is intended (as of the time the first patient is enrolled) to obtain sufficient data and results to support the filing of an application for regulatory approval. (Lengauer (Exact/Thrive) Tr. 170; RX3869 (Cote Expert Report) ¶ 120, n.124.) Depending on the product being tested, a registrational trial is often a randomized, controlled trial, or a prospective, interventional trial. (RX3869 (Cote Expert Report) ¶ 120, n.124.)

Response to Finding No. 317.2

The proposed finding is improper, unreliable, and vague. The second sentence of the proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from a footnote of Dr. Cote's expert report, and Respondents cite no other source to support this portion of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 120 n.124; *see* Order on Post-Trial Findings at 3). This Court should disregard the second sentence of Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "sufficient data and results" and "regulatory approval" are ambiguous. Therefore, this Court should disregard the proposed finding.

> 317.3 For any prospective study, the study size should be big enough to provide sufficient statistical power (with considerations of the associated variabilities) to answer the questions posed by the pre-specified endpoints under investigation, and not too big to avoid exposing participants of unnecessary procedures and treatments and to reduce unnecessary cost. (PX7086 (Cance (ACS) Dep. at 60); Cote Tr. 3806; RX3869 (Cote Expert Report) ¶ 116.)

Response to Finding No. 317.3

The proposed finding is misleading, improper, and vague. Respondents' citation to PX7086, Dr. Cance's deposition, is misleading because Dr. Cance does not provide an opinion on the study size for a prospective study; he specifically states, "that would be a determination between epidemiologists and biostatisticians." (PX7086 (Cance (ACS) Dep. at 60). Dr. Cance does not mention statistical power, associated variabilities, pre-specified endpoints, unnecessary procedures and treatments, or unnecessary cost in the cited testimony.

The only other source that Respondents cite for the proposed finding is Dr. Cote's trial testimony and expert report. Thus, the proposed finding is improper because Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and his trial testimony to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 116; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 116). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed

finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "big enough," "sufficient statistical power," "associated variabilities," and "too big" are ambiguous. Additionally, the term "pre-specific endpoints" is undefined.

318. FDA's requirements for obtaining premarket approval from the FDA may be more stringent than for a test developer to commercialize an LDT: an LDT can be launched by demonstrating results of a case-control study. (Cote Tr. 3824.) FDA is likely to only consider results from well-controlled clinical studies in "a significant portion of the target population" that will demonstrate that the test "will provide clinically significant results." (RX3220 (FDA) at 3; 21 CFR § 860.7.)

Response to Finding No. 318

Complaint Counsel objects to the proposed finding because it is incorrect, unsupported, vague, confusing, misleading, and improperly cites expert testimony.

The proposed finding is incorrect and unsupported because it says the "FDA is likely to only consider results from well-controlled clinical studies in 'a significant portion of the target population." But the FDA publication cited (RX3220) does not say clinical studies must be conducted ***in*** a significant portion of the target population. The publication says there must be "valid scientific evidence, that in a significant portion of the target population, the use of the device … will provide clinically significant results." (RX3220 at 3).

The proposed finding is vague in stating that "an LDT can be launched by demonstrating results of a case-control study" because it does not indicate to whom those results purportedly must be demonstrated.

The proposed finding is confusing and misleading because it suggests some form of FDA approval is required for a test developer to launch an LDT.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 318.1 Specifically, for the FDA to approve a cancer screening test it is likely that the developer of a potential cancer screening test would need to conduct a large, prospective, interventional study in asymptomatic patients. (Cote Tr. 3783–85; [redacted] RX3869 (Cote Expert Report) ¶ 117.)

Response to Finding No. 318.1

[redacted]

319. The FDA has said that "[t]here is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results. The valid scientific evidence used to determine the effectiveness of

a device shall consist principally of well-controlled investigations." (RX3220 (FDA) at 3; 21 CFR § 860.7; RX3869 (Cote Expert Report) ¶ 117, n.120.)

Response to Finding No. 319

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

320. In other words, for an early cancer screening test, whose target population comprises asymptomatic individuals who do not have a diagnosis of cancer, the clinical study cannot use samples from cancer patients, but will need to collect fresh samples prospectively from a large enough set of individuals to qualify as "a significant portion of the target population." (RX3220 (FDA) at 3; RX3869 (Cote Expert Report) ¶ 118.)

Response to Finding No. 320

Complaint Counsel objects to the proposed finding because it is vague, incorrect, unsupported, and improperly cites expert testimony.

The proposed finding is vague because it is not clear what "[i]n other words" refers to or what "the clinical study" refers to. It is also vague because it does not define "fresh samples."

The proposed finding is incorrect and unsupported because it says "the clinical study … will need to collect … samples … from a large enough set of individuals to qualify as "a significant portion of the target population." But the FDA publication cited (RX3220) does not say clinical studies must be conducted ***in*** a significant portion of the target population. The publication says there must be "valid scientific evidence, that in a significant portion of the target population, the use of the device … will provide clinically significant results." (RX3220 at 3).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

321. Because the incidence of cancer in an asymptomatic population is only 4 in 1000 individuals, this means that any proposed study will need to include many thousands of such individuals to provide the opportunity to find diverse cancer types and to have enough patients who will be diagnosed with cancer to be statistically valid. (RX3501 (National Cancer Institute) at 2; RX3869 (Cote Expert Report) ¶ 118.)

Response to Finding No. 321

Complaint Counsel objects to the proposed finding because it is vague, unsupported, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague as to what "any proposed study" refers to, the meaning of "many thousands," and the meaning of "diverse cancer types."

The proposed finding is unsupported because the source cited (RX3501) does not contain any information about clinical studies.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

322. Further, the study must be interventional to evaluate whether the early cancer screening test can provide clinically significant results. (Cote Tr. 3783–85, 3793–94, 3804–05; RX3869 (Cote Expert Report) ¶ 118.)

Response to Finding No. 322

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing

such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

323. In this case, "clinically significant results" will likely include a determination that a higher than expected proportion of the diagnosed cancers are detected at early, potentially curable stage, and may even require follow-up of these patients to determine if early diagnosis and intervention did indeed result in higher than expected cure rates. (RX3869 (Cote Expert Report) ¶ 119).

Response to Finding No. 323

Complaint Counsel objects to the proposed finding because it is vague, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague because it does not define "higher than expected" or explain what that term stands in relation to.

This Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence, leaving the proposed finding unsupported.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

324. Such clinical studies will take months of planning, one or more years of recruiting participants at multiple sites, testing and analysis of samples, diagnostic follow-up to rule in or out cancer, further therapeutic intervention for those that are diagnosed with cancer, multiple years of follow-ups, and at least multiple hundreds of millions of dollars in cost over a minimum of 5-7 years. (Cote Tr. 3783–85, 3793–94, 3804–05; RX3869 (Cote Expert Report) ¶ 119.)

Response to Finding No. 324

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading to the extent it suggests that MCED test developers are in any way behind or not making progress on developing their MCED tests.

[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

> 324.1 This would not include the years of work and expense that would be needed to develop a potential multi-cancer screening test in the first place. [redacted] RX3869 (Cote Expert Report) ¶ 119.)

Response to Finding No. 324.1

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

325. As a result, completion of successful clinical studies in a population covering the intended use of a cancer screening product is one of the biggest hurdles for an early cancer screening test. (Cote Tr. 3783–85, 3793–94; RX3869 (Cote Expert Report) ¶ 120.)

Response to Finding No. 325

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague because it is not clear what "[a]s a result" refers to, and the meaning of "in a population covering" is not clear.

The proposed finding is misleading to the extent it suggests [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

[redacted]

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

[redacted]

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

325.1 [redacted]

Response to Finding No. 325.1

[redacted]

[redacted]

[redacted]

325.2 [redacted]

Response to Finding No. 325.2

[redacted]

[redacted]

326. Further, the results from a clinical study of a screening test for a single specific cancer cannot be used to support a screening test for a different cancer type or multiple cancer types. (RX3869 (Cote Expert Report) ¶ 121.)

Response to Finding No. 326

Complaint Counsel objects to the proposed finding because it is vague and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer

expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague because it begins with "Further." It is also vague because it does not identify the "screening test for a single specific cancer" or the "screening test for a different cancer type or multiple cancer types."

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

> 326.1 For a retrospective, case-control study, only the healthy samples may be re-used to evaluate the efficacy of the new test, because samples from the cancer cohort would not have the new cancer or cancers under investigation. (RX3869 (Cote Expert Report) ¶ 121.)

Response to Finding No. 326.1

Complaint Counsel objects to the proposed finding because it is vague and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer

expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague regarding what is meant by "the healthy samples," "re-used," and "the new test." It also does not identify or specify the "new cancer or cancers under investigation."

[redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

> 326.2 As for a prospective, interventional study, the results of an earlier trial on a single cancer cannot be used because the intervention being analyzed for the new cancer types covered by the new screening test will be different from the intervention in the original study. (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 121.)

Response to Finding No. 326.2

Complaint Counsel objects to the proposed finding because it is confusing, vague, misleading, and against the weight of the evidence, and it improperly cites expert testimony, Dr.

Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is confusing because it begins with "As for a prospective, interventional study."

The proposed finding is vague because does not define what type of "results" it is referring to.

The proposed finding is misleading to the extent it suggests that test developers will be unable to conduct prospective interventional clinical trials on multiple cancers at once. Moreover, it is against the weight of the evidence that, for example, Thrive completed a large interventional study of CancerSEEK involving the multi-cancer screening of 10,000 women called DETECT-A. (Lengauer (Third Rock Ventures) Tr. 163-65; Conroy (Exact) Tr. 1704). DETECT-A was an exploratory prospective interventional study. (Conroy (Exact) Tr. 1703).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

[redacted]

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding 327. [redacted]

Response to Finding No. 327

[redacted]

[redacted]

327.1 [redacted]

Response to Finding No. 327.1

[redacted]

[redacted]

3. **Addition of a New Cancer to An Existing Test**

328. Even once you have an existing cancer screening test, it does not become easier to add additional cancers. (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123.)

Response to Finding No. 328

Complaint Counsel objects to the proposed finding because it is unsupported, vague, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is unsupported because the source cited [redacted]

The proposed finding is vague regarding what "even once you have" and "easier" mean.

The proposed finding's claim that "even once you have an existing cancer screening test, it does not become easier to add additional cancers" is against the weight of the evidence. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding any validation phase Freenome incorporates into its MCED development. This Court should disregard this evidence.

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted].

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-

known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

328.1 As Dr. Cote testified, going through the majority of the development steps for a single-cancer screening test does not put a cancer screening test developer in a position where they're ahead in developing a cancer screening test for a different cancer:

> The development of biomarkers for a particular cancer will not be adequate for other cancers. While there may be overlap, one still needs to go through all of the [development] steps. If . . . the test developer has made the decision that they've already undergone biomarker discovery with the assay that they have, they still need to go through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer, and then has to go through a prospective trial depending on which cancer is being targeted.
>
> (Cote Tr. 3787.)

Response to Finding No. 328.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague regarding what "the majority of the development steps" and "a position where they're ahead" mean.

The proposed finding is misleading to the extent it suggests that developing a single cancer screening test does not provide a platform on which to efficiently develop a multi-cancer screening test.

The proposed finding is against the weight of the evidence that MCED developers are efficiently developing muti-cancer screening tests in parallel with or building on single-cancer screening tests. [redacted]

[redacted] **a** [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding developing an MCED test in parallel with or building from a single-cancer screening test. This Court should disregard this evidence.

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

> 328.2 Should the FDA adopt a relaxed approach to additional cancers, it would be a significant retreat from its longstanding practice to only consider studies of "a significant portion of the target population" that will demonstrate that the test "will provide clinically significant results." (RX3220 (FDA) at 3; 21 CFR § 860.7; RX3869 (Cote Expert Report) ¶ 123).

Response to Finding No. 328.2

Complaint Counsel objects to the proposed finding because it is vague, incorrect, unsupported, misleading, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is vague regarding what "a relaxed approach" means.

The proposed finding is incorrect and unsupported because it says the "FDA is likely to only consider results from well-controlled clinical studies in 'a significant portion of the target population." But the FDA publication cited (RX3220) does not say clinical studies must be conducted ***in*** a significant portion of the target population. The publication says there must be "valid scientific evidence, that in a significant portion of the target population, the use of the device … will provide clinically significant results." (RX3220 at 3).

The proposed finding is misleading to the extent it suggests that developing a single cancer screening test does not provide a platform on which to efficiently develop a multi-cancer screening test.

The proposed finding is against the weight of the evidence that MCED developers are efficiently developing muti-cancer screening tests in parallel with or building on single-cancer screening tests. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding developing an MCED test in parallel with or building from a single-cancer screening test. This Court should disregard this evidence.

[redacted]

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

329. It would take much longer for a prospective, interventional clinical study to demonstrate the efficacy of the cancer screening test in asymptomatic population, and then for the FDA to approve the LDT test as an IVD test (whether as a single-site or as a distributable kit). (RX3869 (Cote Expert Report) ¶ 124.) The whole process will likely take seven to ten years, at minimum. (RX3869 (Cote Expert Report) ¶ 124).

Response to Finding No. 329

Complaint Counsel objects to the proposed finding because it is confusing, vague, misleading, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable

The proposed finding is confusing because it says "[i]t would take much longer" but does

not explain longer than what.

The proposed finding is vague as to what "the cancer screening test," "the LDT," and "the whole process" refer to.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding developing an MCED test in parallel with or building from a single-cancer screening test. This Court should disregard this evidence.

[redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding

H. Exemplary Clinical Oncology Testing Workflow

330. To the extent that a cancer screening test developer uses Illumina's NGS product, the sequencing step is only one part of a multi-step workflow. (Aravanis (Illumina) Tr. 1829–33; Berry (Illumina) Tr. 814–21; RX3869 (Cote Expert Report) ¶ 125.)

Response to Finding No. 330

The proposed finding is misleading, unsupported, vague, and it improperly cites expert testimony, Dr. Cote is not qualified to provide expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading to the extent it implies that NGS sequencing—and in particular Illumina NGS—is not a critical step in MCED testing, upon which other steps are dependent. The proposed finding is against the weight of significant evidence showing that Illumina NGS is a critical upstream input to MCED testing. (*See* CCFF ¶¶ 1019-1211). The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

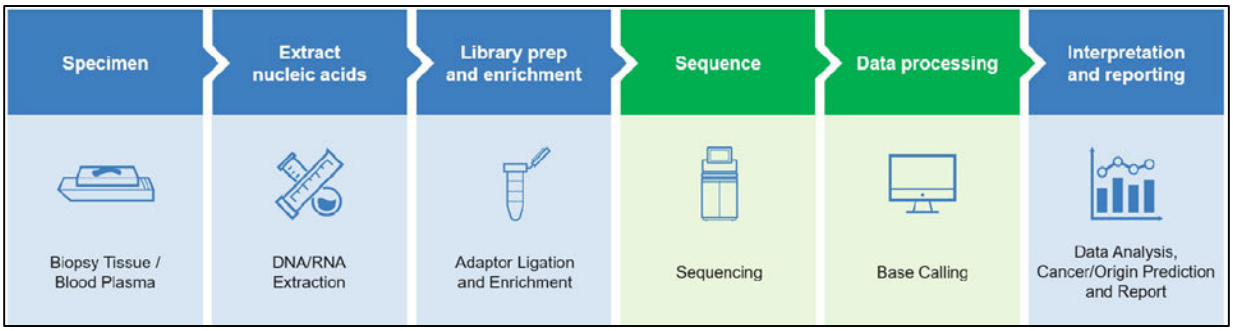
The proposed finding is vague because the term "multi-step workflow" is ambiguous and undefined.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding developing an MCED test in parallel with or building from a single-cancer screening test. This Court should disregard this evidence.

The proposed finding is unreliable because [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

331. As shown in the below figure, sequencing comprises only one step in the overall testing workflow. (RX3860 (Cote Expert Report) ¶ 125, Figure 3.)

Figure 4: Testing Workflow



Response to Finding No. 331

The proposed finding is misleading, against the weight of the evidence, improper, unreliable, and vague.

The proposed finding is misleading to the extent it implies that NGS sequencing—and in particular Illumina NGS—is not a critical step in MCED testing, upon which other steps are dependent. The proposed finding is against the weight of significant evidence showing that Illumina NGS is a critical upstream input to MCED testing. (*See* CCFF ¶¶ 1019-1211).

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 126; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 126). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed factual finding, in contravention of this Court's Order, . This Court should disregard Respondents' proposed finding.

The proposed finding is unreliable because [redacted]

[redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the term "overall testing workflow" is ambiguous and undefined.

332. The steps are (i) specimen collection, (ii) sample preparation (nucleic acid extraction), (iii) library preparation, all of which are involved in preparing the sample, (iv) sequencing, (v) data processing and (vi) data interpretation/reporting. (Aravanis (Illumina) Tr. 1829–1833; Berry (Illumina) Tr. 814–21; RX3869 (Cote Expert Report) ¶ 126.)

Response to Finding No. 332

The proposed finding is misleading, against the weight of the evidence, unsupported, unreliable, and vague.

The proposed finding is misleading to the extent it implies that NGS sequencing—and in particular Illumina NGS—is not a critical step in MCED testing, upon which other steps are dependent. The proposed finding is against the weight of significant evidence showing that Illumina NGS is a critical upstream input to MCED testing. (*See* CCFF ¶¶ 1019-1211).

The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The only other source that the proposed finding relies on is Dr. Cote's report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 126). Yet Dr. Cote is not qualified to provide expert opinion testimony [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "specimen collection," "sample preparation," "nucleic acid extraction," and "library preparation" are undefined. Additionally, it is not clear what "the steps" refers to. Therefore, this Court should disregard the proposed finding

333. For any test that uses NGS sequencing, only two of these six steps involve NGS instruments. (RX3869 (Cote Expert Report) ¶ 126; Aravanis (Illumina) Tr. 1829–33; Berry (Illumina) Tr. 814–21.)

Response to Finding No. 333

The proposed finding is misleading, unsupported, vague, and it improperly cites expert testimony, Dr. Cote is not qualified to provide expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading to the extent it implies that NGS sequencing—and in particular Illumina NGS—is not a critical step in MCED testing, upon which other steps are dependent. The proposed finding is against the weight of significant evidence showing that

Illumina NGS is a critical upstream input to MCED testing. (*See* CCFF ¶¶ 1019-1211). The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The proposed finding is vague because the term "any test" is ambiguous and undefined.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding developing an MCED test in parallel with or building from a single-cancer screening test. This Court should disregard this evidence.

The proposed finding is unreliable because Dr. Cote is not qualified to provide expert opinion testimony [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court

should not accord Dr. Cote's opinion any weight and should disregard the proposed finding

334. *First*, an appropriate sample specimen is collected, such as a tissue biopsy sample, or blood sample for liquid biopsy. (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814; RX3869 (Cote Expert Report) ¶ 127.)

Response to Finding No. 334

The proposed finding is unsupported, unreliable, vague, and confusing. The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The only other source that the proposed finding relies on is Dr. Cote's report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 127). Yet Dr. Cote is not qualified to provide expert opinion testimony about [redacted]. In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the term "tissue biopsy" is undefined and the term "appropriate sample specimen" is ambiguous.

The proposed finding is confusing because it begins with "[f]irst" but it is not clear what process it is referring to. Therefore, this Court should disregard the proposed finding

334.1 A blood sample is collected by a phlebotomist. (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814; RX3869 (Cote Expert Report) ¶ 127.) The samples are stored at low temperature and the relevant portion of the sample, such as the abnormal tissue or blood plasma, is separated for further use. (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–20; [redacted]

Response to Finding No. 334.1

[redacted]

[redacted]

335. [redacted]

Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–20; RX3869 (Cote Expert Report) ¶ 128.)

Response to Finding No. 335

[redacted]

335.1 ; Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–15.)

Response to Finding No. 335.1

[redacted]

335.2 This step is commonly referred to as sample preparation, or "sample prep," which is performed by a trained lab technician, and takes about 1 to 2 hours. [redacted] Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814.)

Response to Finding No. 335.2

[redacted]

[redacted]

336. *Third*, the purified nucleic acids undergo library preparation. (Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25; RX3869 (Cote Expert Report) ¶ 129.) Library preparation processes are proprietary to assay developers and are used to transform the purified nucleic acids into a library of DNA/RNA fragments that is capable of being sequenced using a sequencing instrument. (RX3869 (Cote Expert Report) ¶ 129; Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25).

Response to Finding No. 336

The proposed finding is unsupported, unreliable, misleading, and vague. The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The only other source that the proposed finding relies on is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 129). Yet Dr. Cote is not qualified to provide expert opinion testimony about [redacted]. In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by

any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is vague because the terms "purified nucleic acids" and "assay developers" are undefined. Therefore, this Court should disregard the proposed finding.

> 336.1 For short-read sequencers, the DNA/RNA is first fragmented into pieces comprising a length that is suitable for the read-length of the sequencer. (Aravanis (Illumina) Tr. 1830–31; RX3869 (Cote Expert Report) ¶ 129; Berry (Illumina) Tr. 815–25.)

Response to Finding No. 336.1

The proposed finding is misleading, against the weight of the evidence, unsupported, unreliable, and vague.

The proposed finding is misleading to the extent it suggests that MCED testing can be performed on long-read next generation sequencers. The proposed finding is against the weight of significant evidence showing that long-read next generation sequencers are not an option for MCED testing. (*See* CCFF ¶¶ 1346-98).

The proposed finding is also misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive

Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The only other source that the proposed finding relies on is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 129). Yet Dr. Cote is not qualified to provide expert opinion testimony about [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the terms "short-read sequencers" and "read-length" are undefined. Therefore, this Court should disregard the proposed finding.

336.2 Then adaptors suitable for the NGS sequencer, which are either included as part of the proprietary library preparation kit or purchased from one of many providers, are added (*i.e.*, ligated) to the end of the fragmented DNA. (Aravanis (Illumina) Tr. 1830–1831; RX3869 (Cote Expert Report) ¶ 129; Berry (Illumina) Tr. 815–25; PX0091 (Illumina) at 14.)

Response to Finding No. 336.2

The proposed finding is misleading, unsupported, vague and it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on this subject, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The proposed finding is vague because it does not define "adaptors" or explain what "suitable for the NGS sequencer" means.

The only other source that the proposed finding relies on is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 129). This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention

of this Court's Order. Dr. Cote has no personal knowledge regarding the workflow of any MCED test. This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 336.3 For short-read sequencers, the ligated DNA is typically amplified using PCR, using the adaptor sequence as primers. (RX3869 (Cote Expert Report) ¶ 129; Cote Tr. 3743–3756; Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25.)

Response to Finding No. 336.3

The proposed finding is misleading and unsupported, and it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on this subject, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading to the extent it suggests that MCED testing can be performed on long-read next generation sequencers. The proposed finding is against the weight of significant evidence showing that long-read next generation sequencers are not an option for MCED testing. (*See* CCFF ¶¶ 1346-98).

The proposed finding is also misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive

Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The only other source that the proposed finding relies on is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 129). This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding the workflow of any MCED test. This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about [redacted]). In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed

publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 336.4 The adaptor-ligated (and amplified for short-read sequencers) samples are called sequence "libraries." (PX0091 (Illumina) at 14; RX3869 (Cote Expert Report) ¶ 129.)

Response to Finding No. 336.4

The proposed finding is misleading and vague. It is misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is vague because the term "adaptor-ligated" is undefined and the term "amplified" is ambiguous. Therefore, this Court should disregard the proposed finding.

> 336.5 This step is commonly referred to as library preparation, or "library prep," which is performed by a trained lab technician and takes about 2.5 hours for DNA library prep and about 5.5 hours for RNA library prep. (RX3869 (Cote Expert Report) ¶ 129; Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25; PX0091 (Illumina) at 14.)

Response to Finding No. 336.5

The proposed finding is unsupported, unreliable, misleading, and vague. PX0091 and the trial testimony of Mr. Aravanis and Ms. Berry no support for the claim that library preparation is performed by a trained lab technician and takes about 2.5 hours for DNA and about 5.5 hours for RNA. PX0091, Mr. Aravanis, and Ms. Berry to do not identify who performs the library

preparation step or how long this step takes. The source that Respondents rely on for this information is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 129).

Dr. Cote is not qualified to provide expert opinion testimony about [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is vague because the opening phrase "this step" is ambiguous. Therefore, this Court should disregard the proposed finding.

337. *Fourth*, the DNA libraries are sequenced using the NGS sequencers. (RX3869 (Cote Expert Report) ¶ 130; PX0091 (Illumina) at 14; Aravanis (Illumina) Tr. 1831.) This

sequencing step is commonly automated by the sequencer and the sequencing time varies significantly between sequencers. (RX3869 (Cote Expert Report) ¶ 130; Aravanis (Illumina) Tr. 1831.)

Response to Finding No. 337

The proposed finding is unsupported, unreliable, and vague. The second sentence of proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executive Alex Aravanis.

The only other source that Respondents rely on for this portion of the proposed finding is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 130). Yet Dr. Cote is not qualified to provide expert opinion testimony about [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the phrase "varies significantly" is ambiguous. It is also vague in that "the NGS sequencers" are not identified. Therefore, this Court should disregard the proposed finding.

337.1 For example, Thermo Fisher's Ion GeneStudioTM S5 sequencer with Ion 550TM Chip takes about 8.5–11.5 hours, whereas Illumina's NovaSeq 6000 with S4 flow cells takes about 45 hours. (RX3869 (Cote Expert Report) ¶ 130; RX3357 (Illumina) at 6–7; RX3587 (Thermo Fisher) at 1.)

Response to Finding No. 337.1

The proposed finding is misleading, and it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading because it compares only the run times between the Thermo Fisher Ion Torrent sequencers and Illumina NextSeq and NovaSeq sequencers, divorced from the number of reads, accuracy, and cost of the respective runs. [redacted]

The proposed finding is also misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding the workflow of any MCED test. This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about [redacted] In addition, Dr. Cote is not credible ([redacted]), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

338. *Fifth*, the data generated by the sequencer (which varies depending on the type of sequencer) is converted into DNA base sequences, *i.e.*, A, G, C, T, and U for bisulfite converted methylated C. (Berry (Illumina) Tr. 816–17; RX3869 (Cote Expert Report) ¶ 131; Aravanis (Illumina) Tr. 1831–33.) This step is called data processing, and is often conducted at the same time or soon after the sequencing step. (RX3869 (Cote Expert Report) ¶ 131; Aravanis (Illumina) Tr. 1831–33; Berry (Illumina) Tr. 816–17).

Response to Finding No. 338

The proposed finding is confusing, unsupported, unreliable, and vague.

The proposed finding is confusing regarding what it means for "data" to be "converted into" DNA base sequences.

The proposed finding is unsupported to the extent that it purports to speak for the

workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The only other source that Respondents rely on for the proposed finding is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 131). Yet Dr. Cote is not qualified to provide expert opinion testimony about the workflow for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the term "bisulfite converted methylated C" is undefined. Therefore, this Court should disregard the proposed finding.

> 338.1 For example, the data may be image information generated by the fluorescent tags or electrical current information generated by the DNA strand passing through the nanopore. (RX3869 (Cote Expert Report) ¶ 131, n.137; Berry (Illumina) Tr. 819–22.)

Response to Finding No. 338.1

The proposed finding is unsupported, unreliable, and vague. The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executive Nicole Berry.

The only other source that Respondents rely on for the proposed finding is Dr. Cote's

expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 131 n. 137). Yet Dr. Cote is not qualified to provide expert opinion testimony about the workflow for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the opening phrase "for example" is ambiguous. It is unclear what the proposed finding is being provided as an example of. Additionally, the terms "image information," "fluorescent tag," "electrical current information," and "nanopore" are undefined. Therefore, this Court should disregard the proposed finding.

> 338.2 Oxford Nanopore's long-read sequencers can directly detect methylated C and other base modifications because its base-detection sensor is sensitive to such modifications. (RX3869 (Cote Expert Report) ¶ 131, n.138; Cote Tr. 3753; RX3537 (Oxford Nanopore) at 2.)

Response to Finding No. 338.2

The proposed finding is misleading, and it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

[redacted]

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding the workflow of any MCED test or the use of Oxford Nanopore sequencing. This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about the workflow for multicancer screening tests or how NGS fits into that workflow because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

339. *Last*, the sequence data is analyzed and interpreted by the software proprietary to the test developer, often driven by artificial intelligence, to classify the samples with genomic changes, epigenomic modifications, chromosomal changes, and RNA fusions, and a report is

generated showing ultimate results of the test. (RX3869 (Cote Expert Report) ¶ 132; Aravanis (Illumina) Tr. 1831–33, 1837; Berry (Illumina) Tr. 817–18.)

Response to Finding No. 339

The proposed finding is vague and misleading, and it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it begins with "Last" with no explanation of what that means. The proposed finding is also vague because it does not explain what "software proprietary to the test developer" means. It is also vague because it does not define "genomic changes," "epigentic modifications," "chromosomal changes," or "RNA fusions."

The proposed finding is misleading to the extent that it suggests MCED test developers all must follow a uniform library preparation workflow. As Illumina executive Nicole Berry testified at trial, library preparation "is very unique and specific to the particular test provider's sort of approach or methodology to how they actually look at the DNA or RNA and then derive information from it, and so in the context of a multicancer screening assay, you know, GRAIL's approach would follow one particular library preparation method or approach and another player in the space would probably use a totally different one." (Berry (Illumina) Tr. 815).

The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding the workflow or data analysis of any MCED test. This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about the workflow for multicancer screening tests or how NGS fits into that workflow because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and should disregard the proposed finding.

> 339.1 This step is called data interpretation and reporting and can take anywhere from an hour to much longer, depending on the application. (RX3869 (Cote Expert Report) ¶ 132; Aravanis (Illumina) Tr. 1831–33, 1837; Berry (Illumina) Tr. 817–18.)

Response to Finding No. 339.1

The proposed finding is unsupported, unreliable, and vague. The proposed finding is unsupported to the extent that it purports to speak for the workflow of all MCED test developers while relying on the self-serving testimony of Illumina executives Alex Aravanis and Nicole Berry.

The only other source that Respondents rely on for the proposed finding is Dr. Cote's expert report, from which the entire finding has been copied and pasted verbatim. (RX3869 (Cote Report) ¶ 132). Yet Dr. Cote is not qualified to provide expert opinion testimony about the

workflow for multicancer screening tests because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). In addition, Dr. Cote is not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects), and his opinion about the workflow for multicancer screening tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

The proposed finding is vague because the phrases "data interpretation and reporting," "this step," and "much longer" are ambiguous. Therefore, this Court should disregard the proposed finding.

III. THE ONCOLOGY TESTING SPACE

A. GRAIL's Galleri Test

1. Overview of GRAIL's Galleri Test

340. GRAIL has developed a multi-cancer screening test, Galleri, that simultaneously screens for over 50 different types of cancers from a single blood sample. (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100; RX3869 (Cote Expert Report) ¶ 133.)

Response to Finding No. 340

The proposed finding is incomplete and misleading. There is no clinical evidence that Galleri can provide early detection of over 50 cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically

shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted]).

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See, e.g.,* RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.,* CCFF ¶ 6233). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population. Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer

claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021). Therefore, this Court should disregard the proposed finding.

341. Galleri is the first blood-based multi-cancer early screening test to be offered to asymptomatic patients with no history of cancer and was launched in June 2021 as an LDT. (Bishop (GRAIL) Tr. 1322.)

Response to Finding No. 341

The proposed finding is vague and unsupported. The proposed finding is vague because

the terms "offered" and "launched" are undefined and provided without context. The proposed finding is unsupported because the cited source does not mention anything about Galleri being "the first" blood-based multi-cancer early screening test to be offered to asymptomatic patients with no history of cancer. With respect to Galleri's launch date, Respondents cite only to the testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis. Complaint Counsel notes that Grail has made multiple, conflicting, statements about when Galleri was launched as an LDT, including [redacted] May 2021 (Della Porta (Grail) Tr. 460), and June 2021 (Ofman (Grail) Tr. 1322). Therefore, this Court should disregard the proposed finding.

342. Galleri is designed to detect cancer through epigenomic analysis of a single blood draw before a patient ever shows symptoms (*e.g.*, lesions, lumps, or other signs of cancer). (RX3869 (Cote Expert Report) ¶ 133; Bishop (GRAIL) Tr. 1319–21; RX3254 (GRAIL).)

Response to Finding No. 342

Complaint Counsel does not disagree that Galleri is designed to detect cancer before a patient is symptomatic or that the Galleri test itself is based on a single blood draw. The proposed finding is incomplete and misleading, however, to the extent it suggests that no further diagnostic work (beyond a "single blood draw") would be necessary to determine the accuracy of a positive cancer signal reported by Galleri. When assessed in a screening setting involving asymptomatic normal-risk participants, 70 percent of positive Galleri results were falsely positive, meaning the test "detected" a signal for cancer among participants who did not have cancer. *See* CCFF ¶ 6292. Additional diagnostic work is necessary for patients with false positive results to confirm that they did not have cancer. Additional diagnostic work is also necessary for patients for whom Galleri returns a true positive. When asked whether Galleri

could "identify the cancer signal of origin just through the blood," Grail's CEO, Hans Bishop clarified that "the appropriate workup associated with that cancer signal of origin" would be required for confirmation, including the use of ultrasound and biopsy. (Bishop (Grail) Tr. 1387). Mr. Bishop testified at trial that some patients may need to undergo a body scan to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). [redacted] Respondents' expert, Dr. Richard Cote, testified at trial that a physician may need to perform a targeted follow-up screening test on individuals who take the Galleri test. (Cote Tr. 3802-3803).

343. In clinical studies, Galleri has detected over 50 types of cancers, of which 45 do not currently have a recommended screening procedure in the US. (Bishop (GRAIL) Tr. 1373, 1391; RX3285 (GRAIL) at 1; RX3286 (GRAIL) at 2; RX3287 (GRAIL) at 1)

Response to Finding No. 343

The proposed finding is incomplete and misleading. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic screening population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early-stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted]).

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See, e.g.,* RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The proposed finding itself uses the term "screening procedure," confirming that the relevant metric is Galleri's ability to screen for cancers in asymptomatic patients. The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.,* CCFF ¶ 6233). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010

(E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

Finally, Complaint Counsel notes that the proposed finding is unreliable because Respondents cite only the self-serving testimony of a Grail executive and three Grail press releases (RX3285, RX3286, and RX3287) for the proposed finding, rather than the "clinical studies" themselves. Therefore, this Court should disregard the proposed finding.

344. Notably, Galleri has high sensitivity and specificity for forms of cancer that have no routine screening options, are usually detected at late stage and thus are often lethal. (Cote Tr. 3795–96; 3799–3801, RX3114 (Chen et al., 2021 at 1); RX0744 (GRAIL) at slide 60.)

Response to Finding No. 344

The proposed finding is vague and unsupported. The proposed finding is vague because the terms "high sensitivity and specificity," and "usually" are undefined. The proposed finding is unsupported because nowhere in the cited testimony of Dr. Cote does he characterize the sensitivity or specificity of Galleri as "high." RX3114 fails to support the proposed finding. RX3114 is an article by Chen et. al, which references the CCGA study (Liu et al), but is not the actual study reporting results. RX3114 refers vaguely to the specificity and of "targeted methylation analysis" of "multiple [undisclosed] cancer types" in the CCGA study. RX3114 does not characterize the "sensitivity" of Galleri as high; there is no discussion of sensitivity whatsoever in the cited material. The citation to RX0744 also fails to support the proposed finding. The cited slide, part of an internal Grail slide deck, has no discernable connection to proposed finding: the slide does not so much as mention "sensitivity," "specificity," "routine screening options," cancer staging, or lethality rates. Complaint Counsel does not dispute that cancers detected at late stage are frequently lethal.

Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (*i.e.* in an asymptomatic screening population). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at

10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Grail admits as much itself. [redacted]

345. Unlike certain other cancer screening test developers, who are taking a mutational approach to detecting cancer (including as one type of biomarker in a multiomics approach) (Cote Tr. 3810, 3844, 3852, 3870–71), the Galleri test detects cfDNA shed by cancer cells using a targeted methylation assay. (Bishop (GRAIL) Tr. 1319–21; (Ofman (GRAIL) Tr. 3286–87; [redacted] Specifically, GRAIL looks at regions of the genome for clusters of CpG sites that are methylated or unmethylated. (Bishop (GRAIL) Tr. 1320; RX0744 (GRAIL) at slides 30–40; [redacted]

Response to Finding No. 345

The proposed finding is incorrect, misleading, and against the weight of the evidence to the extent that it implies that Grail "discovered" MCED testing. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

345.1 Methylation is a form of epigenomic change: rather than change the code of a DNA molecule, methylation occurs when methyl groups attach to DNA and "affect which genes are turned on and off", which in turn "affects what the cell becomes and how it behaves". (Aravanis (Illumina) Tr. 1882.) Methylation is considered "a hallmark of cancer because they tend to turn tumor suppressor genes off and they tend to turn tumor promoter genes on." (Ofman (GRAIL) Tr. 3286.)

Response to Finding No. 345.1

Complaint Counsel has no specific response to the proposed finding.

345.1.1 As Dr. Alex Aravanis explained, "if you think, for example, of a lung cell versus a liver cell, they have the same DNA in them. That's not different. What's different is the methylation patterns, so the places in the DNA that are methylated or unmethylated, which is this chemical change, is very different even though the underlying DNA is the same. And so this fingerprint really determines . . . what a cell is and what a tissue [is]. There [are] about 30 million methylation sites . . . in the human genome." (Aravanis (Illumina) Tr. 1882.)

Response to Finding No. 345.1.1

Complaint Counsel has no specific response to this proposed finding.

346. GRAIL developed a machine learning algorithm that differentiates abnormal tumor cfDNA methylation patterns from normal cfDNA methylation patterns. (RX3083 (Bryce et al., 2021) at 1; [redacted]

Response to Finding No. 346

Complaint Counsel has no specific response to the proposed finding.

346.1 As Dr. Josh Ofman explained: "[Galleri] looks at over a million of these methylation sites in over a hundred thousand regions of the genome. And so then you take these patterns, and [subjected them] across cancer types and across cancer stages to train a machine learning algorithm to discriminate what is a cancer signal from what is a

noncancer signal. And we made sure that the control group had lots of confounding indications and diseases to create a lot of biological noise so that our classifier was effectively trained and we didn't have models that were overfit. So once you subject these patterns to the machine learning algorithm, it will classify the pattern as either a cancer-like signal or a noncancer signal. And then if a cancer signal gets detected, the patterns then get subjected to a second step, which is another classifier, which looks and weights different features from these patterns to predict the tissue of origin or where this cancer signal came from in the body, so we call it a cancer signal origin or a tissue of origin." (Ofman (GRAIL) Tr. 3287.)

Response to Finding No. 346.1

Complaint Counsel has no specific response to this proposed finding.

347. [redacted]

Response to Finding No. 347

[redacted]

348. To date, GRAIL has developed three versions of Galleri. (Ofman (GRAIL) Tr. 3291–94.)

Response to Finding No. 348

The proposed finding is incorrect and misstates the testimony of Dr. Ofman. Nowhere in the cited record does Dr. Ofman testify that Grail has developed three versions of Galleri. Moreover, this proposed finding is inconsistent with Respondents' Proposed Finding No. 351, which states that Grail "is currently developing a third version of Galleri." (*see* RCPFF ¶ 351). Therefore, this Court should disregard the proposed finding.

349. Version 1 ("v1") of Galleri was used in GRAIL's Circulating Cell-Free Genome Atlas substudy (CCGA2) and the PATHFINDER Study. (Ofman (GRAIL) Tr. 3291–94.)

Response to Finding No. 349

Complaint Counsel does not disagree with the proposed finding.

350. [redacted] RX3869 (Cote Expert Report) ¶ 135.) GRAIL launched v2 of the Galleri test as an LDT in June 2021. (Bishop (GRAIL) Tr. 1322; RX3869 (Cote Expert Report) ¶ 135.)

Response to Finding No. 350

The proposed finding is vague and unsupported.

The second sentence of the proposed finding is vague because the term "launched" is undefined and provided without context. With respect to Galleri's launch date, Respondents cite only to the testimony of a Grail executive and Dr. Cote's report, uncorroborated by any ordinary course documents or analysis. Complaint Counsel notes that Grail has made multiple statements about when Galleri was launched as an LDT, including [redacted] May 2021 (Della Porta (Grail) Tr. 460), and June 2021 (Ofman (Grail) Tr. 1322). In fact, Mr. Bishop testified that there were

practices that had access to Galleri prior to June of 2021. (Bishop (GRAIL) Tr. 1322).

Therefore, this Court should disregard the proposed finding.

351. GRAIL is currently developing a third version of Galleri, which GRAIL intends to submit for FDA approval. (PX7083 (Bishop (GRAIL) Dep. at 204–05); Ofman (GRAIL) Tr. 3301–02.)

Response to Finding No. 351

Complaint Counsel does not disagree with the proposed finding.

351.1 The changes in the third version are geared toward reducing the amount of sequencing that needs to be done in order to lower costs; all of the same biomarkers are being interrogated as in v2, (Ofman (GRAIL) Tr. 3301–02.)

Response to Finding No. 351.1

Complaint Counsel does not disagree with the proposed finding.

352. [redacted] at 14; RX3869 (Cote Expert Report) ¶ 135.)

Response to Finding No. 352

[redacted]

[redacted]

353. [redacted] RX3869 (Cote Expert Report) ¶ 135.)

Response to Finding No. 353

Complaint Counsel does not disagree with the proposed finding.

354. Depending on the type of cancer, Galleri v1 can detect Stage I and Stage II cancers (i.e., its sensitivity) between 18–43% of the time overall, and a sensitivity of 43.9% for all cancer types, at 99.3% specificity. (RX3430 (Liu et al., 2020) at 1; RX0744 (GRAIL) at 54; [redacted] RX3869 (Cote Expert Report) ¶ 136.)

Response to Finding No. 354

The proposed finding is vague, incorrect, and misleading. The proposed finding is vague because the terms "[d]epending on the type of cancer," "can detect," "of the time overall," and "all cancer types" are undefined.

The proposed finding cites to data from Grail's CCGA-2 substudy. The proposed finding is misleading and incorrect to the extent it suggests that reported sensitivities from the CCGA-2 substudy are indicative of how Galleri would actually perform when used in its intended use population (i.e. in an asymptomatic screening population). CCGA did not involve a real-world

population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). The authors of the CCGA-2 substudy themselves acknowledge: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (Liu, et al., 2020)). Grail admits as much itself. [redacted]

The proposed finding is also incorrect to the extent it suggests that "sensitivity of 43.9% for all cancer types, at 99.3 specificity" references the sensitivity and specificity of Galleri for Stage I and II cancers specifically in the CCGA-2 substudy. In fact, the 43.9 percent sensitivity number referenced is the reported sensitivity for Stage I-III cancers in the CCGA-2 substudy (not Stages I and II) and the 99.3 percent specificity number referenced is the reported specificity across all cancer stages (not Stages I and II specifically). (*See* RX3430 at 1 (Liu et al., 2020) at 1). Neither RX0744 [redacted] provides specific numbers related to the reported Stage I and II sensitivities or specificities in the CCGA-2 substudy.

Finally, this Court ordered that experts shall not be cited to "support factual propositions

that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. This Court should disregard the citation to Dr. Cote and the proposed finding.

355. Galleri's current sensitivity rate for v2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 136.) This includes cancers that have no screening test today, are usually only found at an advanced stage and thus have a high mortality rate. (Cote Tr. 3795–96; 3799–3801; RX3869 (Cote Expert Report) ¶ 136.)

Response to Finding No. 355

The proposed finding is vague, incorrect, misleading, and relies in part on improper expert opinion. The proposed finding is vague because the terms "current," "sensitivity rate," "its test," "all cancer types," "across stages," "screening test," "advanced," and "high" are undefined.

The proposed finding cites to data from Grail's CCGA-3 substudy. The proposed finding is incorrect and misleading to the extent it suggests that reported sensitivities from the CCGA-3 substudy are indicative of the "current" sensitivity of Galleri as an actual "test" that is "available as an LDT." CCGA did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Results from CCGA-3 are thus not informative of Galleri's actual performance in its intended use population (i.e. in an asymptomatic screening population). The authors of the CCGA-3 substudy themselves acknowledge that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., 2021) (RX3409 is the actual paper by Klein et al on which RX3408 is based). Grail admits as much itself. [redacted]

[redacted]

The proposed finding is also misleading to the extent that, combined with RPFF ¶ 354, it suggests that Galleri's sensitivity at detecting Stage I-II cancers (in the non-representative, non-screening population involved in CCGA) improved from v1 to v2. For Stage I and Stage II cancers, the reported sensitivity of v2 of Galleri actually declined relative to v1 of Galleri. In CCGA-3 the reported sensitivity was 16.8 percent for Stage I cancer (vs. 18 percent for v1 in CCGA-2) and 40.4 percent for Stage II cancer (vs. 43 percent for v1 in CCGA-2). (Compare RX3409 at 009 (E.A. Klein, et al., 2021) with RX3430 at 001 (Liu et al., 2020)).

[redacted] This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. This Court should disregard the citations to Dr. Cote and the proposed finding.

Complaint Counsel does not disagree that v2 of Galleri is the version that Grail has made available as an LDT.

356. These results suggest that the Galleri test as currently constructed has the ability to save lives by detecting dangerous cancers at an earlier, potentially curable stage. (RX3869 (Cote Expert Report) ¶ 136.)

Response to Finding No. 356

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague and unreliable. The proposed finding is vague because the terms "these results," "ability," "dangerous," and "earlier" are ambiguous and undefined.

The proposed finding is unreliable because Respondents cite only to the paid testimony of Dr. Cote for support. Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)). In addition, Dr. Cote's opinion about the "ability" of the Galleri test "to save lives" is unreliable because Dr. Cote performed no actual analysis to support his opinion. Accordingly, his opinion has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This proposed finding of fact should be disregarded.

357. Galleri's specificity for v2 of its test is 99.5%. (RX3409 (Klein et al., 2021) at 5; RX3408 (Klein et al., 2021 AACR Presentation) at 10; RX0872 (GRAIL) at 9, 13; RX3869 (Cote Expert Report) ¶ 136.)

Response to Finding No. 357

The proposed finding is misleading to the extent it suggests that reported specificity from the CCGA-3 substudy is indicative of the specificity of Galleri as a screening "test" for asymptomatic individuals. CCGA did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Results from CCGA-3 are thus not informative of how Galleri would actually perform when used in its intended use population (i.e. in an asymptomatic screening population). The authors of the CCGA-3 substudy themselves acknowledge that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., 2021) (RX3409 is the actual paper by Klein et al on which RX3408 is based). Grail admits as much itself. [redacted].

358. At this time, Galleri is not meant as an alternative or replacement to standard cancer screening procedures, but rather as a complement to recommended screenings, designed to detect more cancers earlier while minimizing the harms that may come from a false positive result. (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136.)

Response to Finding No. 358

The proposed finding is vague because the terms "meant" and "standard cancer screening procedures" are not defined and the terms "earlier" and "minimizing" are provided without context. Therefore, this Court should disregard the proposed finding.

359. Because the risk of cancer increases significantly after age 50, GRAIL expects the use of Galleri to be concentrated in an elevated risk population, for example, in individuals over the age of 50, when the risk of cancer increases significantly. (PX0043 (GRAIL) at 5, 110; *see also* PX7083 (Bishop (GRAIL) Dep. at 25); [redacted]

Response to Finding No. 359

The proposed finding is vague because the terms "concentrated" and "elevated risk population" and "significantly" are not defined. Therefore, this Court should disregard the proposed finding. Complaint Counsel does not dispute that the risk of cancer is greater for individuals above the age of 50 relative to individuals below the age of 50.

2. **Galleri Test Workflow**

360. To run the Galleri test, GRAIL's CLIA-certified laboratory follows a multi-step workflow that follows a standard procedure used for many NGS-based tests. (RX3025 (Alexander et al., 2021) at 4; [redacted]

[redacted]

(RX3025 (Alexander et al., 2021) at 4; [redacted]

Response to Finding No. 360

The proposed finding is vague because the terms "standard procedure" and "many NGS-based tests" are undefined. Therefore, this Court should disregard the proposed finding.

361. *First,* Galleri uses a blood biopsy specimen collected from participants. Blood plasma in the specimen is separated from blood cells. (RX3025 (Alexander et al., 2021) at 4; Bishop (GRAIL) Tr. 1375–76; [redacted]

Response to Finding No. 361

Complaint Counsel has no specific response to this proposed finding.

362. *Second*, cfDNA (*i.e.*, the nucleic acids) are isolated through sample preparation by GRAIL. (Bishop (GRAIL) Tr. 1379–80; [redacted]

Response to Finding No. 362

Complaint Counsel has no specific response to this proposed finding.

363. *Third*, the sample undergoes library preparation and enrichment by GRAIL. (Bishop (GRAIL) Tr. 1379–80; [redacted]

Response to Finding No. 363

Complaint Counsel has no specific response to this proposed finding.

363.1 GRAIL fragments the DNA samples into smaller pieces of DNA and adds specialized adapters to both ends of the DNA fragments, which allow the fragments to bind to a flow cell, a surface designed for those DNA fragments to attach to for the purpose of sequencing. (PX7104 (Aravanis (Illumina) Dep. at 117); [redacted]

Response to Finding No. 363.1

Complaint Counsel has no specific response to this proposed finding.

363.2 [redacted]

Response to Finding No. 363.2

Complaint Counsel has no specific response to this proposed finding.

363.3 Like other tests that rely on NGS sequencing, the proprietary steps for GRAIL's test occur in the library prep stage, where GRAIL prepares the samples so that the analytes it seeks to analyze are detected, and at the last phase where GRAIL uses its proprietary algorithm to interpret the base calls that the NGS sequencer has provided. [redacted] Aravanis (Illumina) Tr. 1832–33; [redacted]

Response to Finding No. 363.3

The proposed finding is vague because the terms "other tests that rely on NGS sequencing," "proprietary steps," "library prep stage," "last phase," and "base calls" are undefined and provided without context. Therefore, this Court should disregard the proposed finding.

364. *Fourth*, the prepared sample then is sequenced at GRAIL's laboratory. (Bishop (GRAIL) Tr. 1380; [redacted] GRAIL's laboratory currently uses the Illumina NovaSeq 6000 with an S4 flow cell to process the Galleri assay. (PX7103 (Jamshidi (GRAIL) Dep. at 31); PX7104 (Aravanis (Illumina) Dep. at 168–69); [redacted]

Response to Finding No. 364

Complaint Counsel has no specific response to this proposed finding.

364.1 At this step, the library is loaded onto a flow cell and placed on the sequencer. (Aravanis (Illumina) Tr. 1831; [redacted] The sequencer amplifies the DNA fragments from the sample through "cluster generation," which copies the fragments into millions of copies of single-stranded DNA. (RX0461 (Illumina) at 22–23); [redacted]

Response to Finding No. 364.1

Complaint Counsel has no specific response to this proposed finding.

365. *Fifth*, the sequencer then identifies the nucleotides in the fragments from the sample ("base calling") and gives the predicted accuracy of each base call. (Berry (Illumina) Tr. 819–22; [redacted]

Response to Finding No. 365

Complaint Counsel has no specific response to this proposed finding.

366. *Sixth*, GRAIL uses its proprietary algorithm (*i.e.*, the classifier) to analyze the raw data from the sequencer to identify the presence of cancer and the origin of the cancer signal.

[redacted] Bishop (GRAIL) Tr. 1380; [redacted] GRAIL also prepares a report for the physician to provide the results of the Galleri test. (Bishop (GRAIL) Tr. 1380–22; [redacted]

Response to Finding No. 366

The proposed finding is misleading to the extent it suggests that Galleri necessarily identifies the presence of cancer when cancer is present or necessarily correctly identifies the origin of the cancer signal. Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (i.e. in an asymptomatic screening population). Similarly, reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population. Grail's CCGA study did not involve a real-world population, but rather was a case-control study that involved individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Grail's PATHFINDER study was incomplete as of the time of trial and had released only "interim" results. (*See* RPFF ¶ 402; RX3041 at 1 (Grail) (Interim Results of Pathfinder, 2021)). Therefore, this Court should disregard the proposed finding.

367. GRAIL uses a number of suppliers for inputs used in performing the Galleri test. [redacted] RX3869 (Cote Expert Report), Appendix C.)

Response to Finding No. 367

The proposed finding is vague, incomplete, and misleading. The proposed finding is vague because it does not define the terms "a number of supplies" or "inputs." The proposed finding is incomplete and misleading to the extent it suggests that Grail does not rely on Illumina as its sole-source provider for necessary inputs used in performing the Galleri tests. In Grail's Form S-1 filed with the Securities and Exchange Commission, Grail detailed in the "Risk Factors" section, "[w]e rely on Illumina, Inc. as a sole supplier for our next-generation sequencers and associated reagents. . . ." (PX0043 at 011 (Grail 2020 Form S-1); *see also* Bishop (Grail) Tr. 1336). In its Form S-1, Grail also acknowledged, "Any disruption in Illumina's operations or breach of our supply-related agreements would impact our supply chain and laboratory operations as well as our ability to develop and commercialize our products, including Galleri and DAC." (PX5049 at 29 (Grail Form S-1, Sept. 9, 2020)). Therefore, this Court should disregard the proposed finding.

3. **Galleri's Clinical Studies**

368. Since 2016, GRAIL has undertaken four major clinical studies to validate its test, while another clinical study was enrolling participants at the time of trial. (Cote Tr. 3789–94; Ofman (GRAIL) Tr. 3291–94; RX0744 (GRAIL Core Slide Deck) at 46–47; RX3869 (Cote Expert Report) ¶ 138.)

Response to Finding No. 368

The proposed finding is vague because the terms "major," "validate," and "its test" are undefined. Therefore, this Court should disregard the proposed finding.

368.1 These four clinical studies involved combined total of nearly 140,000 participants in North America and the United Kingdom. (RX3430 (Liu et al., 2020) at 3; Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 71; (RX3291 (GRAIL) at 1.)

[redacted]

Response to Finding No. 368.1

The proposed finding is vague, unreliable, incomplete, and improper. The proposed finding is vague because "nearly" is undefined. The proposed finding is unreliable because, other than RX3430, Respondents cite to second-hand accounts for the number of participants in particular studies, rather than to the studies themselves or the actual tallies of participants registered at ClinicalTrials.gov. Complaint Counsel does not disagree that Grail has enrolled over 130,000 participants in clinical studies. (*See* CCFF ¶ 5309). The actual number of participants enrolled in CGA, STRIVE, SUMMIT, and PATHFINDER based on data from ClinicalTrials.gov, however, is less than 135,000. (*See* PX0390 ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021).

The proposed finding includes an improper demonstrative exhibit. This Court ordered that the parties "not cite to demonstrative exhibits as substantive evidence." *See* Order on Post-Trial Findings at 3. [redacted]

a. Circulating Cell-Free Genome Atlas Study

369. The Circulating Cell-Free Genome Atlas Study ("CCGA"), started in August 2016, is GRAIL's foundational study. (Ofman (GRAIL) Tr. 3291–92; RX3287 (GRAIL) at 2; RX0867 (GRAIL) at 3; [redacted] RX3869 (Cote Expert Report) ¶ 139.)

Response to Finding No. 369

The proposed finding is vague, unreliable, mischaracterizes the testimony of Dr. Ofman, and violates the Court's Order. The proposed finding is vague because the term "foundational" is undefined. The proposed finding mischaracterizes the testimony of Dr. Ofman because Dr. Ofman neither provides a date on which CCGA "started" nor characterizes CCGA as "foundational" in the portion of the transcript cited by Respondents.

The term "foundational" appears in RX3287, which appears to be a Grail press release printed off the internet. This source is unreliable in that it provides neither citation nor context for the claim that CCGA is "foundational." Slide 3 of RX0867, a Grail presentation of unknown purpose, depicts the letters "CCGA" on a timeline under the year 2016. No context is given for this depiction. The proposed source is unreliable.

[redacted]

Respondents mischaracterize RX0744 to the extent they suggest it supports any part of the proposed finding; the pages cited on RX0744 neither provide a date on which CCGA "started" nor characterize CCGA as "foundational."

The only remaining source cited for the proposed finding is the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

370. It is a prospective, multicenter (142 sites), case-control, observational study with longitudinal follow-up. (RX3430 (Liu et al., 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48.) It is believed to be the largest case-control study that's been for early detection.. (Ofman (GRAIL) Tr. 3291.)

Response to Finding No. 370

The proposed finding is vague, unreliable, mischaracterizes evidence cited, is misleading, and contravenes the Court's Order on Post-Trial Findings. The proposed finding is vague because the terms "it," "longitudinal," and "early detection" are undefined. The proposed finding is also vague because it fails to disclose who supposedly "believes" "it" to be "the largest case-control study that's been for early detection."

The proposed finding mischaracterizes the evidence cited. Respondents' primary citation for the proposed finding is page 1 of RX3430. To the extent the "it" in the proposed finding refers to the CCGA study, the cited material fails to support the assertion that the study was "multicenter," the number of "sites" associated with the study, the study's status as "observational," or anything to do with "longitudinal follow-up." The proposed finding also mischaracterizes the testimony of Dr. Ofman. To the extent the "it" in the proposed finding refers to the CCGA study, nowhere in the cited portion of the trial transcript does Dr. Ofman assert that the study was "multicenter," testify about the number of "sites" associated with the study, describe the study "observational," or mention anything about "longitudinal follow-up."

[redacted]

[redacted]

371. It involved the collection of de-identified biospecimens (blood and tissue samples) and clinical data from 142 clinical networks in the United States and Canada, involving the enrollment of 15,254 participants and a cost of about $30 million. (RX3430 (Liu et al., 2020) at 3; [redacted] RX3869 (Cote Expert Report) ¶ 139.) Of those participants, 44% did not have a known cancer diagnosis while 56% had a newly diagnosed cancer ranging early to late-stage (Stage I-IV). (RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 139.)

Response to Finding No. 371

The proposed finding is vague, misleading, and mischaracterizes the cited evidence. The proposed finding is vague because the terms "it," "clinical networks," "involving," "about," and "newly-diagnosed" are undefined.

If "it" in the proposed finding refers to the CCGA study, the proposed finding is misleading to the extent it suggests that the 15,254 participants "enrolled" in CCGA were actually part of the analysis populations of the CCGA-2 and/or CCGA-3 studies. In fact, only 3,087 samples from CCGA enrollment made their way into the final training an analysis in CCGA-2. *See* RX3430 at 005, Figure 3 (Liu et al., 2020). Nephron Healthcare Investment Research explained that "A Significant Number of CCGA Samples Were Excluded from Analysis" in the CCGA-2 sub-study and "the magnitude" of the excluded samples was "surprising." (PX4178 (Grail) at 021 ("Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020)). The analysis set for the CCGA-3 substudy involved 4,077 participants. *See* RX3409 at 004, Figure 2 (Klein et al., 2021).

The proposed finding mischaracterizes the evidence. The citation to RX3430 does not mention any cost for the study. [redacted]

[redacted] The only remaining source cited for the proposed finding is the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 371.1 "[F]or cancers where there is no existing screening methodology, those cancers tend to present very late stage in disease, so finding . . . patients with early-stage cancers is very hard and very rare." (Aravanis (Illumina) Tr. 1917–18.) In order to do so, GRAIL had to set up 142 trial sites to find rare examples of individuals with these unscreened cancers at early-stage disease. (Aravanis (Illumina) Tr. 1918.) It was "unprecedented in scale and complexity and cost to do that." (Aravanis (Illumina) Tr. 1918.) Because of this effort, Galleri is able to detect 45 cancer types which have no existing screening methodology. (Aravanis (Illumina) Tr. 1918.)

Response to Finding No. 371.1

Complaint Counsel does not disagree that it is more difficult to detect early-stage cancers than late-stage cancers in screening applications. The remainder of the proposed finding is vague, unreliable, and misleading. The proposed finding is vague because the phrases "very late," "early-stage," "unscreened," "unprecedented," and "because of this effort" are undefined. The proposed finding is unreliable because Respondents cite only to testimony of a party executive uncorroborated by ordinary course documents or analysis.

The proposed finding is unreliable because Dr. Aravanis does not have foundation to speak to the scale, complexity, and cost of the CCGA study relative to other studies conducted by other companies of which he lacks personal knowledge and for which he cites no factual basis.

The proposed finding is also misleading to the extent that it suggests that the cancer arm of the CCGA study was limited to "individuals with . . . early-stage disease." In fact, 44 percent of the participants in the cancer arm of the CCGA-2 study were cancer patients whose cancer had already progressed to Stages III-IV (23 percent of cancer participants had Stage IV cancer), (RX3430 (Grail) at 006-007 (Liu, et. al, 2020) and 42 percent of the participants in the cancer arm of the CCGA-3 study were cancer patients whose cancer had already progressed to Stages III-IV (22 percent of cancer participants had Stage IV cancer). (RX3409 (Grail) at 006, Table 1 (Klein et. al, 2021).

The proposed finding is also misleading to the extent it suggests that there has been any clinical demonstration that Galleri provides early detection of 45 cancer types "which have no existing screening methodology" in a screening setting. There is no clinical evidence that Galleri can provide early detection of 45 cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted]).

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population.

Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See, e.g.,* RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.,* CCFF ¶ 6223). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection

and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021). With the exception of the proposition that it is more difficult to detect early-stage cancers than late-stage cancers in screening applications, this Court should disregard the proposed finding.

> 371.2 The study was also unique because the samples were prospectively collected. As Dr. Cote explained: "[The] case-control trial was actually prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples. (Cote Tr. 3794–95.)

Response to Finding No. 371.2

The proposed finding is vague, unreliable, incorrect, and misleading. The proposed finding is vague because the terms "unique," "prospectively collected," "strict protocol," "all these samples," and "similar to an actual clinical collection of samples are undefined."

The proposed finding is unreliable because Dr. Aravanis does not have foundation to speak to the uniqueness of the CCGA study procedures relative to other studies conducted by

other companies of which he lacks personal knowledge and for which he cites no factual basis. Indeed, the proposed finding is incorrect to the extent it suggests that the prospective "collection" of samples makes CCGA "unique." [redacted] According to Grail's intelligence, Burning Rock initiated a 14,000-patient prospective clinical study in China for a pan-cancer early detection test. (PX4139 (Grail) at 001 (Email from A. Tosti, Grail, to E. Mann, Grail, May 28, 2020)).

The proposed finding is also misleading to the extent that the reference to the prospective "collection" of samples in CCGA is intended to suggest that CCGA was a true prospective study and/or an interventional study. It was not. As explained in a November 2020 investment research produced from Grail's files, "None of GRAIL's studies represent a truly prospective, real-world study." (PX4178 (Grail) at 025, Nephron Healthcare Investment Research, "Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020). [redacted] CCGA assessed the ability of Galleri to detect cancer signals in patients who had already been diagnosed with cancer previously. (*See* CCFF ¶¶ 6238-6245). Therefore, this Court should

disregard the proposed finding.

372. GRAIL collected up to 80 mL of blood from each participant, while also collecting tissue samples of the individuals with a known cancer diagnosis. (RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 139.)

Response to Finding No. 372

Complaint Counsel has no specific response to the proposed finding, but adds for completeness, that tissue samples of individuals with cancer were submitted "when available." (RX3430 at 003 (Liu et al., 2020)).

373. In the CCGA study, GRAIL followed up with its participants for a period of 5 years. (RX0744 (GRAIL) at 48; RX3869 (Cote Expert Report) ¶ 139.)

Response to Finding No. 373

The proposed finding is vague, misleading, and mischaracterizes the evidence. The proposed finding is vague because the term "followed up" is undefined. The proposed finding is misleading because the use of the past tense in the term "followed up" suggests that the follow-up period of the CCGA study has been completed. The citation to Slide 48 of RX0744 as supportive of this notion mischaracterizes the evidence. Slide 48 of RX0744 merely states that the "Study Design" for CCGA involves "Follow-up for 5 years," not that such follow up has been completed. The only other source cited for the proposed finding is the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence. Indeed, Dr. Cote's only proposed support for his statement appears to be the same underlying document Respondents also cite, which as noted above fails to support the proposed finding. Therefore, this Court should disregard the proposed finding.

374. GRAIL designed the CCGA study to determine if cfDNA sequencing, in combination with machine learning, would be able to (1) detect a large number of cancers at a high enough specificity to be used as an early cancer screening test for the general population, and (2) determine the tissue of origin of detected cancers (an essential tool in determining next-steps once cancer has been detected in a patient). (RX3430 (Liu et al.,. 2020) at 3; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48; RX3869 (Cote Expert Report) ¶ 139.)

Response to Finding No. 374

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, misleading, mischaracterizes the cited evidence, and contravenes the Court's Order on Post-Trial Findings. The proposed finding is vague because the term "tool" is undefined and its relation to "determin[ing] the tissue of origin of detected cancers" is unclear.

Additionally, Respondents cite the authors of the CCGA-2 study (Liu et al, 2020) for the proposition that the CCGA study was designed to determine if cfDNA sequencing, in combination with machine learning, would be able to (1) detect a large number of cancers at a high enough specificity to be used as an early cancer screening test for the general population." (emphasis added). This statement is misleading and mischaracterizes the evidence. In fact, Liu et al, 2020 state that the CCGA study was designed to determine whether genome-wide cfDNA sequencing in combination with machine learning could detect and localize a large number of cancer types at sufficiently high specificity to be considered for a general population-based cancer screening program." (RX3430 at 3 (emphasis added). Indeed, the authors of the CCGA-2 sub-study explicitly state that: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)).

The proposed finding is also misleading and mischaracterizes the evidence to the extent it attributes the vague statement about tissue of origin determination being "an essential tool" to the

authors of the CCGA-2 study. The material cited in RX3430 does not support such a characterization. The proposed finding also mischaracterizes the testimony of Dr. Ofman. Nothing in his cited testimony supports the specific factual propositions in the proposed finding. The proposed finding also mischaracterizes RX0744. The slides cited in RX0744 do not support the specific language of the proposed finding.

[redacted]

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote (Respondents miscite the paragraph as ¶ 139 rather than ¶ 140). This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

375. CCGA is expected to be completed in March 2024; in total, CCGA study will have spanned nearly eight years. (RX0744 (GRAIL) at 47; RX3869 (Cote Expert Report) ¶ 140.)

Response to Finding No. 375

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is unsupported to the extent it relies solely on improper expert opinion. Slide 47 of RX0744 states merely that the "expected completion" of CCGA is March 2024. The cited

slide does not mention any study start date or study duration.

The only other source cited for the proposed finding is the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

Complaint Counsel has no specific response to Respondents' assertion that CCGA is expected to be completed in March 2024.

376. The design of CCGA involves three sub-studies. (Ofman (GRAIL) Tr. 3291–95; RX3869 (Cote Expert Report) ¶ 140.)

Response to Finding No. 376

Complaint Counsel does not disagree with the proposed finding.

377. The first sub-study was designed to discover and differentiate cancer biomarkers, to determine the most effective way to identify multiple cancers and their signal of origin, and train GRAIL's machine learning algorithms to detect those biomarkers. (Ofman (GRAIL) Tr. 3291–94.); RX3410 (Liu et al., 2018) at 1; RX3869 (Cote Expert Report) ¶ 140.)

Response to Finding No. 377

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is unsupported, misleading, and mischaracterizes the cited evidence. Dr. Ofman says nothing about cancer signal of origin in the pages of the trial transcript cited. Respondents' attribution of such a statement to him mischaracterizes his testimony and is therefore misleading. RX3410 also fails to support the proposed finding; the source does not state that the first sub-study was designed to determine "the most effective way" to identify multiple cancers and cancer localization. Respondents' citation to RX3410 is thus misleading and mischaracterizes the evidence.

The only other source cited for the proposed finding is the actual source from which the

proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

378. GRAIL then proceeded to "development" in CCGA2, which was designed to perform further analysis, training, and validation of v1 of the Galleri test: specifically, to discover methylation patterns of identified cancer biomarkers associated with known cancer types, and then train and validate a machine-learning classifier to differentiate methylation patterns associated with cancer vs. non-cancer as well as predict the origin of the cancer signal. (Ofman (GRAIL) Tr. 3292; RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 141.)

Response to Finding No. 378

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, unsupported, misleading, and mischaracterizes the stated evidence. The proposed finding is vague because the terms "development," "validation" and "known cancer types" are undefined. The proposed finding mischaracterizes the testimony of Dr. Ofman and is therefore misleading. Nowhere in the portion of the transcript cited does Dr. Ofman state that Grail "proceeded to 'development'" of Galleri in CCGA-2, or anything similar. The proposed finding also mischaracterizes RX3430. On the page cited, the CCGA-2 authors (Liu et al.,) state that "a methylation-based assay was selected for further development in this second sub-study." (RX3430 at 3 (emphasis added)). The proposed finding is unsupported and misleading to the extent it suggests that the CCGA-1 study was not also related to "development." [redacted]

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

> 378.1 This training and validation was to demonstrate the feasibility of detecting cancer and predicting signal of origin with minimal false positives. (RX3430 (Liu et al., 2020) at 3; RX0744 (GRAIL) at slide 46; RX3869 (Cote Expert Report) ¶ 141.)

Response to Finding No. 378.1

The proposed finding is vague and mischaracterizes cited evidence. The proposed finding is vague because the term "minimal false positives" and "validation" are not defined. The proposed finding mischaracterizes RX3430, which does not mention "minimal false positives," but instead states merely that CCGA was "designed to determine whether genome-wide cfDNA sequencing in combination with machine learning could detect and localize a large number of cancer types at sufficiently high specificity to be considered for a general population-based cancer screening program." (RX3430 at 3 (emphasis added)).

The proposed finding is also misleading because — like numerous of Respondents' other proposed findings — it is copied and pasted verbatim from Dr. Cote's report, even though Respondents do not quote Dr. Cote, and it represents only his opinion rather than market realities. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

> 379. The third sub-study was designed to further validate the assay for multi-cancer detection and the identification of the cancer signal of origin. (Ofman (GRAIL) Tr. 3292–93; RX3408 (Klein et al., 2021) at 6; RX3869 (Cote Expert Report) ¶ 141.)

Response to Finding No. 379

The proposed finding is vague and incomplete. The proposed finding is vague because

the terms "further validate" and "the assay" are undefined. The proposed finding is incomplete because it omits that the third substudy, CCGA-3, [redacted] Therefore, this Court should disregard the proposed finding.

(i) CCGA1

380. In CCGA1, GRAIL investigated a variety of approaches to determine which approach performed the best for purposes of an early cancer detection test. (Ofman (GRAIL) Tr. 3291–92; RX3869 (Cote Expert Report) ¶ 142.)

Response to Finding No. 380

The proposed finding is vague, unreliable, misleading, against the weight of evidence, and mischaracterizes the testimony of Dr. Ofman. The proposed finding is vague because the terms "investigated," "variety of approaches," "performed the best" and "early cancer detection test" are undefined and provided without context. For example, it is not clear if Respondents are referring to MCED tests specifically or to all cancer detection tests.

The proposed finding mischaracterizes the testimony of Dr. Ofman. Dr. Ofman testified that Grail determined, based on CCGA-1 that methylation patterns were "the strongest and most robust way to detect cancer signals in the blood," not that Grail conducted an investigation to determine the best "approach" to "early cancer detection" generally. (Ofman (Grail) Tr. 3292 (emphasis added)). The proposed finding is also misleading and against the weight of evidence to the extent it suggests that Grail's current methylation-only approach to multi-cancer early detection is superior to approaches by other MCED developers that combine methylation with other approaches, such as proteomics. Grail's decision that methylation was a stronger "approach," on its own, compared to other "approaches" on their own does not imply that methylation is superior to a combination of methylation and other approaches. Indeed, the proposed finding is against the weight of evidence because [redacted]

[redacted]

The proposed finding is also misleading because — like numerous of Respondents' other proposed findings — it is copied and pasted verbatim from Dr. Cote's report, even though Respondents do not quote Dr. Cote, and it represents only his opinion rather than market realities. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

381. CCGA1 focused exclusively on a single analyte, blood, and investigated multiple types of biomarkers, including cancer-derived mutations (single nucleotide variants and small variants), chromosome alterations (copy number and fragment features such as length and endpoint analysis through whole-genome sequencing), and methylation patterns (through whole genome bisulfite sequencing). (Ofman (GRAIL) Tr. 3291–92; RX3430 (Liu et al., 2020) at 1–3; RX3869 (Cote Expert Report) ¶ 142.)

Response to Finding No. 381

Complaint Counsel has no specific response to the proposed finding.

382. Through the CCGA1 sub-study, GRAIL concluded that interrogating genome-wide methylation patterns using bisulfite sequencing outperformed targeted sequencing and whole-genome sequencing approaches to detect cancer-derived mutations or chromosome alterations. (Ofman (GRAIL) Tr. 3291–92; RX3430 (Liu et al., 2020) at 3, 9; RX3410 (Liu et al., 2018) at 1.)

Response to Finding No. 382

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague and misleading. The proposed finding is vague because the term "outperformed" is undefined. The proposed finding is also misleading to the extent it suggests that Grail's current methylation-only approach to multi-cancer early detection is superior to approaches by other MCED developers that combine methylation with other approaches, such as proteomics. Grail's internal conclusion that interrogating genome-wide methylation patterns using bisulfite sequencing, on its own, "outperformed" other approaches, on their own, does not imply that methylation is superior to a combination of methylation and other approaches. [redacted]

382.1 In other words, GRAIL concluded through the CCGA1 sub-study that interrogating methylation was the best approach for detecting cancer signals and that some regions of the genome and their methylation status were more informative than others with regards to cancer signals. (Ofman (GRAIL) Tr. 3291–92; PX7103 (Jamshidi (GRAIL) Dep. at 60–67; RX3869 (Cote Expert Report) ¶ 142.)

Response to Finding No. 382.1

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, unreliable, misleading, against the weight of evidence, mischaracterizes

the testimony of Dr. Ofman, and relies on improper expert opinion. The proposed finding is vague because the terms "best approach" and "detecting cancer signals" are undefined and provided without context. The proposed finding mischaracterizes the testimony of Dr. Ofman. Dr. Ofman testified that Grail determined, based on CCGA-1 that methylation patterns were "the strongest and most robust way to detect cancer signals in the blood," not that Grail conducted an investigation to determine the "best approach" to "early cancer detection" generally. (Ofman (Grail) Tr. 3292 (emphasis added)). The proposed finding is also misleading and against the weight of evidence to the extent it suggests that Grail's current methylation-only approach to multi-cancer early detection is superior to approaches by other MCED developers that combine methylation with other approaches, such as proteomics. Grail's decision that methylation was a stronger "approach," on its own, compared to other "approaches" on their own does not imply that methylation is superior to a combination of methylation and other approaches. Indeed, the proposed finding is against the weight of evidence because [redacted]

This Court ordered experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here,

Respondents not only cite, but directly quote Dr. Cote to support supposedly factual propositions about what "Grail concluded" in contravention of this Court's Order. Dr. Cote has no personal knowledge of what "Grail concluded." This Court should disregard this evidence and the proposed finding.

383. Also, GRAIL found that methylation patterns are highly effective at identifying the origin of the cancer signals. (Ofman (GRAIL) Tr. 3291–92; RX3550 (Oxnard et al., 2019) at 1; RX3429 (Liu et al., 2019) at 2; RX3869 (Cote Expert Report) ¶ 142.)

Response to Finding No. 383

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, unreliable, mischaracterizes the evidence, and relies on improper expert opinion. The proposed finding is vague because the term "highly effective," "the origin," and "the cancer signals" are undefined and provided without context. The proposed finding mischaracterizes the testimony of Dr. Ofman. Nowhere in the cited portion of the trial transcript does Dr. Ofman state that methylation patterns are "highly effective" at identifying the origin or cancer signals. Indeed, Dr. Ofman says nothing at all about cancer signal origin on the pages cited. RX3550 is a half-page abstract and not a complete article by Oxnard et al. As such, it is unreliable. The source does not state that methylation patterns are "highly effective" at identifying the origin of cancer signals, but rather comments on the "accuracy" of "TOO localization" in a particular early study. The proposed finding mischaracterizes RX3429. RX3429 states that "[i]ncorporating data from a large methylation database improved TOO performance in multiple cancer types," but does not state that methylation patterns are "highly effective" at identify the origin of cancer signals.

This Court ordered experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents not only cite, but directly paste in Dr. Cote's report language to support supposedly

factual propositions about what "Grail found" in contravention of this Court's Order. Dr. Cote has no personal knowledge of what "Grail found." This Court should disregard this evidence and the proposed finding.

384. GRAIL selected a targeted methylation-based assay (Galleri v1) for further development in CCGA2. (Ofman (GRAIL) Tr. 3291–92; RX3869 (Cote Expert Report) ¶ 142.)

Response to Finding No. 384

Complaint Counsel does not disagree with the proposed finding.

385. In total, CCGA1 took two years (though GRAIL had already commenced research and biomarker discovery before commencing CCGA1). (Ofman (GRAIL) Tr. 3294; RX3869 (Cote Expert Report) ¶ 142.)

Response to Finding No. 385

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, mischaracterizes the testimony of Dr. Ofman and relies on improper expert opinion. The proposed finding mischaracterizes the testimony of Dr. Ofman. Nowhere on page 3294 of the trial transcript does Dr. Ofman state that CCGA1 "took two years," nor does he mention anything about Grail having "commenced research and biomarker development discovery before commencing CCGA1."

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the report of Dr. Cote. This Court ordered experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents not only cite, but directly paste in Dr. Cote's report language to support supposedly factual propositions about the timeline of Grail's research in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

(ii) CCGA2

386. The second CCGA sub-study, CCGA2, was designed to perform analysis, training, and validation of the Galleri v1 test, using the Galleri v1 assay developed using the findings from CCGA1. (Ofman (GRAIL) Tr. 3291–92; RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 143.)

Response to Finding No. 386

Complaint Counsel does not disagree with the proposed finding.

387. CCGA2 included 6,689 participants, which were divided into a training set of 4,720 participants and an independent validation set of 1,969 participants, of which 4,316 participants (training: 3052; validation: 1264) were ultimately included in the final analysis population. (RX3430 (Liu et al., 2020) at 6–7; RX3869 (Cote Expert Report) ¶ 143.)

Response to Finding No. 387

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is incorrect, misleading, and mischaracterizes RX3430 (Lie et al, 2020) to the extent it suggests that the 4,316 participants included the final analysis population were from CCGA-2 enrollment. In fact, only 3,087 samples from CCGA enrollment made their way into the final training and analysis in CCGA-2; these samples were supplemented by 1,229 samples from the separate STRIVE study. (*See* RX3430 at 005, Figure 3 (Liu et al., 2020) (disclosing that of the 3052 samples in the final analysis "training" population, 892 were taken from STRIVE, and of the 1264 validation sample in the final analysis "validation" population, 337 were taken from STRIVE (4316 – 892 – 337 = 3,087)). As Nephron Healthcare Investment Research explained, "A Significant Number of CCGA Samples Were Excluded from Analysis" in the CCGA-2 sub-study and "the magnitude" of the excluded samples was "surprising." (PX4178 (Grail) at 021 ("Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020) (further explaining that"CCGA-2 started with 4,841 samples – of which 3,087 made their way into the final training and analysis" and that "[i]nterestingly, to increase the overall sample size, GRAIL included 2,202 samples from the STRIVE study [and] [o]f these, 1,220 samples made their way

into the final analysis and validation.")). Therefore, this Court should disregard the proposed finding.

388. The results of the CCGA2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (RX3430 (Liu et al., 2020) at 1, 10.)

Response to Finding No. 388

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, incomplete, and misleading. The proposed finding is vague because the terms "Galleri," "capable of detecting," and "false-positive rate" are undefined and provided without context. The proposed finding is incomplete and misleading to the extent it suggests that CCGA-2 provides evidence of how Galleri would perform when used as intended (*i.e.* use as a screening test in an asymptomatic population). There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early-stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted].

[redacted] Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

[redacted] Indeed, 24 percent of participants in the cancer arm of the CCGA2 study were Stage IV cancer patients (RX3430 at 6). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the cited CCGA-2 substudy – which Respondents rely upon for their 50-cancer claim – make this point explicitly in their article, cautioning that: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)).

For similar reasons, Grail cannot say today what the performance of its MCED test will be in Galleri's intended use population (i.e. in an asymptomatic screening population). Grail admits as much itself. [redacted]

[redacted]

The proposed finding is also misleading in its use of the term "false positive rate" to the extent it suggests that 99 percent of cancer predictions were accurate in the CCGA-2 substudy. (*See* PX4178 (Grail) at 023 ("Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020) (noting that the CCGA-2 authors used "false positive" to mean "the proportion of false-positive results among persons thought to be cancer-free (0.7%), whereas the data actually shows that the fraction of positive tests shown to be falsely positive is 49%" and, further, that the CCGA-2 authors' "chosen incidence of cancer influenced the false positive rate, which would be higher than 49%.")). [redacted] Therefore, this Court should disregard the proposed finding.

389. Galleri v1 achieved a sensitivity of 43.9% for all cancer types. (RX3430 (Liu et al., 2020) at 1,10; RX0744 (GRAIL) at 70; RX3869 (Cote Expert Report) ¶ 143.) Galleri v1 demonstrated a cancer signal of origin prediction accuracy of 93%. (RX3430 (Liu et al., 2020) at 1, 9; RX0744 (GRAIL) at 68; RX3869 (Cote Expert Report) ¶ 143.)

Response to Finding No. 389

The proposed finding is vague, incomplete, and misleading. The proposed finding is vague because the terms "achieved," "for all cancer types" and "cancer signal of origin prediction accuracy" are undefined and provided without context. The proposed finding is incomplete and misleading to the extent it suggests that CCGA-2 provides evidence of how

Galleri would perform when used as intended (*i.e.* use as a screening test in an asymptomatic population). Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (i.e. in an asymptomatic screening population) or how accurate Galleri's predictions will be at localizing cancer in the intended use population.

[redacted] Indeed, 24 percent of participants in the cancer arm of the CCGA2 study were Stage IV cancer patients (RX3430 at 6). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). [redacted] Grail admits as much itself. [redacted]

[redacted]

Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31.

[redacted]

Additionally, the proposed finding is incomplete because it omits to mention that

Galleri's reported tissue of origin accuracy was worse for Stage I-II cancers than for Stage III-IV cancers in CCGA (*See* RX3430 at 6, Figure 4 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2]). This fact further suggests that Galleri's CSO performance will be worse in an asymptomatic screening population that does not include previously diagnosed Stage III and Stage IV cancer patients, as the CCGA study did. Also, the denominator for Galleri's tissue of origin accuracy in CCGA-2 is artificially limited to just those cases in which the original cancer prediction was correct (excluding false positives) and, of those, just those cases in which Galleri actually made a tissue of origin prediction. (*See* RX3430 at 009). Therefore, this Court should disregard the proposed finding.

390. CCGA2 took another two years. (Ofman (GRAIL) Tr. 3294; RX3869 (Cote Expert Report) ¶ 143.)

Response to Finding No. 390

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, mischaracterizes the testimony of Dr. Ofman, relies on improper expert opinion, and is therefore unsupported. The proposed finding is vague because the terms "took" and "another" are vague and provided without context. The proposed finding mischaracterizes the testimony of Dr. Ofman. Nowhere on page 3294 of the trial transcript does Dr. Ofman state that CCGA2 "took another two years."

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's

Order. The Court should disregard this evidence and the proposed finding.

(iii) CCGA3

391. CCGA3, the third CCGA sub-study, was designed to evaluate Galleri's performance by testing a large cohort of samples from participants with and without cancer and to validate Galleri v2 as a multi-cancer early detection test capable of population-wide testing. (Ofman (GRAIL) Tr. 3292; RX0744 (GRAIL) at 47–48; PX7069 Bishop (GRAIL), IHT at 80; RX3869 (Cote Expert Report) ¶ 144.)

Response to Finding No. 391

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, mischaracterizes the evidence cited, relies on improper export opinion, and is incomplete. The proposed finding is vague because the terms "large," "with and without," "validate," "capable of," and "population-wide" are undefined and provided without context.

The proposed finding mischaracterizes the testimony of Dr. Ofman. Dr. Ofman did not testify that CCCA-3 was designed "to evaluate Galleri's performance," that CCGA-3 involved "a large cohort of samples," or that CCGA-3 was designed to validate Galleri "as a multi-cancer early detection test capable of population-wide testing" in the trial testimony cited. The proposed finding also mischaracterizes RX0744; the cited slides do not state that CCGA-3 was designed "to evaluate Galleri's performance," that CCGA-3 involved "a large cohort of samples," or that CCGA-3 was designed to validate Galleri "as a multi-cancer early detection test capable of population-wide testing." Indeed, the cited slides on RX0744 are not even about CCGA-3 specifically. The proposed finding also mischaracterizes the testimony of Mr. Bishop. Mr. Bishop did not testify that the CCGA-3 involved "a large cohort of samples," or that CCGA-3 was designed to validate Galleri "as a multi-cancer early detection test capable of population-wide testing."

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote. This

Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. Dr. Cote has no personal knowledge of what CCGA "was designed" to accomplish. The Court should disregard this evidence.

[redacted].

Complaint Counsel does not disagree that CCGA-3 was the third CCGA sub-study or that CCGA-3 was split into cancer and non-cancer arms. However, this Court should disregard the remainder of this proposed finding for the reasons stated above.

392. CCGA3 ultimately reported that GRAIL's Galleri v2 test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, sensitivity of 51.5% for all cancers, and a signal of origin prediction accuracy of 88.7%. (RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144.)

Response to Finding No. 392

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, misleading, and incomplete. The terms "ultimately reported," "achieved," "across," "false-positive rate," "for all cancers," and "signal of origin prediction accuracy" are vague and undefined.

The proposed finding is incomplete and misleading to the extent it suggests that CCGA-3 provides evidence of Galleri's real-world performance (*i.e.* when use as a screening test in an asymptomatic population). There is no clinical evidence that Galleri can provide early detection

of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. [redacted] Likewise, Grail cannot say today what the sensitivity, specificity, false positive rate, or tissue localization accuracy of its MCED test will be in Galleri's intended use population or how accurate Galleri's predictions will be at localizing cancer in the intended use population.

[redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). Grail admits as much itself. [redacted]

[redacted]

The fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population. [redacted]

Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31.

[redacted] *see also* PX4178 (Grail) at

024 ("Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020) (explaining that, in practice, the sensitivity for late stage cancers is irrelevant as they are likely detectable by symptoms)).

The suggestion that the reported 51.5% sensitivity number in CCGA-3 applies to "all cancers" is also misleading – even in the non-representative, non-screening setting in which Galleri was assessed. The sensitivity of Galleri varied by cancer type and cancer stage. Specifically, Galleri's overall sensitivity for Stage I cancers was just 16.8 percent in CCGA-3, and Galleri's overall sensitivity for Stage II cancers was just 40.4 percent. (RX3409 at 009).

[redacted]

Additionally, the cancer signal or origin ("CSO") accuracy numbers reported in CCGA-3 overstate the extent to which Galleri was able to correctly identify the location of cancer – even in the non-representative, non-screening setting in which Galleri was assessed. Specifically, the denominator for Galleri's reported CSO accuracy in CCGA-3 (which produced the 88.7% statistic) was artificially limited to just those cases in which the original cancer prediction was correct (excluding false positives). But a CSO prediction cannot be said to be "correct" or "accurate" in instances where a patient has no cancer at all.

Additionally, Grail counts Galleri's CSO predictions as being correct even in instances when Galleri does not actually identify the location of the underlying cancer. One of Galleri's cancer signal of origin categories is "Neuroendocrine Cells of Lung or Other Organs" (RX3409 at 10 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)

[CCGA-3]). The supplementary materials to the CCGA-3 study disclose that the "neuroendocrine" CSO label actually includes instances of cancer from twelve different CCGA cancer classes: pancreas, gallbladder, esophagus, stomach, bladder, urothelial tract, cervix, colon/rectum, head and neck, lung, prostate, and uterus (RX3773 at 31, Figure S1 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)). These cancers are spread out across the entire human body; a "correct" CSO prediction of "neuroendocrine cells of lung or other organs" is thus not actually a specific tissue of origin prediction at all. The CCGA-3 substudy authors acknowledge this, stating that CSO predictions that fall into this catch-all category "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). Therefore, this Court should disregard the proposed finding.

393. Galleri v2 is the test currently being offered by GRAIL commercially as an LDT. (Ofman (GRAIL) Tr. 3317; RX3869 (Cote Expert Report) ¶ 144.)

Response to Finding No. 393

Complaint Counsel has no specific response to the proposed finding.

b. PATHFINDER

394. Starting in December 2019, GRAIL began enrolling participants for its prospective, interventional multi-center study PATHFINDER. (RX3044 (GRAIL) at 1–2 RX3869 (Cote Expert Report) ¶ 145.)

Response to Finding No. 394

Complaint Counsel has no specific response to the proposed finding.

395. PATHFINDER's primary goal is to assess the extent and types of diagnostic testing required to achieve a diagnostic resolution after a patient has received a cancer screening

test result that indicates "Signal Detected", meaning the potential presence of cancer, along with a predicted or indeterminate tissue of origin. (Ofman (GRAIL) Tr. 3295–98; RX0611 (GRAIL) at 9; RX3869 (Cote Expert Report) ¶ 145.)

Response to Finding No. 395

Complaint Counsel does not disagree with the proposed finding.

396. Another goal of PATHFINDER is to test the performance of Galleri's v1 assay and review patient experiences and satisfaction with the test. (Ofman (GRAIL) Tr. 3295–98, 3299–3300; RX0611 (GRAIL) at 9; RX3869 (Cote Expert Report) ¶ 145.)

Response to Finding No. 396

Complaint Counsel has no specific response to the proposed finding.

397. It is the first study in which Galleri results were returned to participants and their clinicians to allow them to undertake the necessary diagnostic steps necessary for a proper cancer diagnosis after receiving the results of a Galleri test. (Ofman (GRAIL) Tr. 3296–97 RX3869 (Cote Expert Report) ¶ 145.)

Response to Finding No. 397

Complaint Counsel does not disagree with the proposed finding but notes, for completeness, that PATHFINDER was the first *Grail* study to return results to participants and their clinicians. It was not the first study of an MCED test to return results to participants and their clinicians. Grail had not published the final results of PATHFINDER as of trial.

398. This study allowed GRAIL to evaluate the implementation of Galleri in clinical practice. (Ofman (GRAIL) Tr. 3296–97; RX3869 (Cote Expert Report) ¶ 145.)

Response to Finding No. 398

The proposed finding, which consists of language copied and pasted verbatim from Dr.

Cote's report, is vague and misleading. The proposed finding is vague because the terms "[t]his study," "implementation of Galleri," and "clinical practice" are undefined. The proposed finding is misleading because its use of the past tense ("allowed") suggests that the PATHFINDER study had been completed. [redacted] Therefore, this Court should disregard the proposed finding.

> 398.1 "The purpose of PATHFINDER was very clear. We needed to show -- after the clinical validation of our test, we needed to better understand how positive results were going to get worked up, how the test was actually going to get implemented in clinical practice. And we also wanted to understand whether the positive predictive value, which again is the key clinical measure, that we saw in the CCGA study, how that would translate into the real world, and so that was going to be a core aspect of PATHFINDER. PATHFINDER was not designed or powered to replicate the sensitivity of Galleri or to try to find, you know, all the cancers that Galleri can find, because that would require hundreds of thousands of people. So it was really a feasibility study about implementing Galleri into actual clinical practice." (Ofman (GRAIL) Tr. 3296–97.)

Response to Finding No. 398.1

The proposed finding is vague, misleading, and unreliable. The proposed finding is vague because the terms and phrases "clinical validation of our test," "worked up," "key clinical measure," and "that we saw," and "all the cancers that Galleri can find" are undefined. The proposed finding is unreliable as to positive predictive value being the "the key clinical measure" (whatever that means) because Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis.

The proposed finding is also misleading because its use of the past tense ("was really a feasibility study") suggests that the PATHFINDER study had been completed. [redacted] Complaint Counsel does not dispute that, notwithstanding CCGA, Grail lacked understanding of how its test would actually be

implemented in clinical practice or how performance metrics from CCGA (which was a non-representative case-control study involving participants with previous cancer diagnoses) would "translate into the real world." Complaint Counsel also does not dispute Dr. Ofman's concession that it would potentially "require hundreds of thousands of people" to assess Galleri's ability to detect (or not detect) the cancers from the cancer arm of the CCGA study in an asymptomatic screening population.

> 398.2 The results of PATHFINDER so far have been promising:
>
> Q. And was GRAIL happy with the interim results of the PATHFINDER study?
>
> A. Yes. It was really remarkable that it performed pretty close to as we predicted it would, and the PPV that we've seen thus far on the interim seems to be very well-aligned with what we've seen in prior studies. And that's really important because in this field, you know, it's littered with companies that do these small, underpowered studies, case-control studies -- I have lots of examples -- where they put it into actual clinical care and the tests don't work. And so, you know, there's a lot of skepticism about that, and so it was really important for us to show that the robust CCGA study was able to replicate itself under real-world conditions. (Ofman (GRAIL) Tr. 3296–97.)

Response to Finding No. 398.2

The proposed finding is vague, unreliable, incomplete, and misleading. The proposed finding is vague because the terms "promising," "happy," "performed," "pretty close to as we predicted it would," "seems to be," "very well-aligned," "prior studies," "this field," "underpowered," "skepticism about that," "robust," and "replicate itself" are undefined and provided without context. The proposed finding is unreliable because Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis.

The proposed finding is misleading because the term "promising" is an

argument/characterization by Respondents, not a factual statement made by the witness cited. The proposed finding is also misleading because Dr. Ofman's use of the past tense ("performed," "was able to replicate") suggests that the PATHFINDER study had been completed. [redacted]

The proposed finding is also misleading to the extent the citation to Dr. Ofman's testimony that Galleri "performed pretty close to as we predicted it would" in PATHFINDER suggests that Galleri's actual performance was similar to its performance in the CCGA study. [redacted] Dr. Ofman's statement that Galleri performed "pretty close" to Grail's expectations is thus vague, misleading, and proves little.

In fact, Galleri's interim "performance" in PATHFINDER for asymptomatic patients of normal (non-elevated) risk was substantially worse than Galleri's performance in CCGA. The reported interim PPV for normal-risk patients in PATHFINDER was 30. (RX3041 at 004) [redacted]

[redacted]

In addition, Galleri did not detect many early-stage cancers in PATHFINDER. According to the interim results of PATHFINDER, Galleri detected 9 total instances of Stage I-II cancer out of 6629 participants. (RX3041 at 005). Galleri also returned 36 false positive results. (RX3041 at 003). Nine participants wound up undergoing invasive procedures based on falsely positive Galleri results. (RX3041 at 003). [redacted] Thus, Galleri was four times as likely to falsely identify cancer as it was to correctly identify "early stage" cancer (as defined by Dr. Cote), and Galleri was as likely to lead to an unnecessary invasive procedure as it was to correctly identify "early stage" cancer.

Complaint Counsel does not disagree with Dr. Ofman's assessment that "small . . . case-control studies" are not sufficient to establish how clinical tests will perform under real-world conditions. [redacted] For those reasons, Dr. Ofman acknowledged at trial that it is therefore "really important" for Grail to demonstrate the Galleri test's performance "under real-world conditions." (Ofman (Grail) Tr. 3297). With the exception of the specific language noted with which Complaint Counsel does not disagree, this Court should disregard the proposed finding.

398.3 In PATHFINDER, Galleri has detected "13 different types of cancer, and some in their early stages. We found early pancreatic cancer. We found early liver cancer. We found early head and neck cancer. We found a lot of hematologic malignancies. So it was almost like you were standing on the street corner watching

healthy 50-year-olds walk by that had no idea they had cancer and seeing the cancers just light up as they walked by. It was really remarkable." (Ofman (GRAIL) Tr. 3297–98.)

Response to Finding No. 398.3

The proposed finding is vague, unreliable, incomplete, and misleading. The proposed finding is vague because the term "some cancers" is undefined and Dr. Ofman's entire extended simile about standing on a street corner lacks specificity and represents an imagined scenario rather than facts of which he has personal knowledge. The proposed finding is unreliable because Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis.

The proposed finding is incomplete because it omits to mention the fact that only seven of the 13 types of cancer detected in PATHFINDER were Stage I-III cancers. (RX3041 at 005). At most, therefore, Galleri detected seven types early-stage cancers in PATHFINDER. (*See* RX3041 at 005; Cote Tr. 4000-4001 ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."). [redacted] By his definition, Galleri detected only five types early-stage cancers in PATHFINDER. (RX3041 at 005)].

Complaint Counsel does not disagree that Galleri detected 13 different types of cancer in the PATHFINDER study, including "pancreatic cancer," "early liver cancer," "early head and neck cancer" and "hematologic malignancies." [redacted]

With the exception of the specific language noted with which Complaint Counsel does not

disagree, this Court should disregard the proposed finding.

> 398.4 There was no concern that Galleri found 13 different types of cancer rather than 50 in PATHFINDER. To find "all 50 cancers, you know, in a real-world population is going to require hundreds of thousands of people, so PATHFINDER was not designed to do that. PATHFINDER was really designed to understand the specificity of the test and its positive predictive value. So no, we were -- we were thrilled that there was such a diversity of cancers that were found in PATHFINDER." (Ofman (GRAIL) Tr. 3298.)

Response to Finding No. 398.4

The proposed finding is vague, unreliable, misleading, and against the weight of the evidence. The proposed finding is vague because the phrases "There was no concern," "Galleri found," "really designed," and "thrilled" are undefined. The proposed finding is unreliable because Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis.

The proposed finding is incomplete because it omits to mention the fact that only seven of the 13 types of cancer detected in PATHFINDER were Stage I-III cancers. (RX3041 at 005; Cote Tr. 4000-4001 ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."). [redacted] Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31).

The proposed finding is misleading and against the weight of the evidence to the extent it suggests that the primary goal of PATHFINDER was "to understand the specificity of the test

and its positive predictive value." [redacted] Therefore, this Court should disregard the proposed finding.

Complaint Counsel also does not dispute Dr. Ofman's concession that it would potentially "require hundreds of thousands of people" to assess Galleri's ability to detect (or not detect) the cancers from the cancer arm of the CCGA study in an asymptomatic screening population.

399. PATHFINDER recruited 6, 662 participants over the age of 50 and divided them into two different cohorts, a cohort with additional risk of a positive cancer result (3695; ~55% of total enrollment), and another cohort containing participants without any heightened risk (2934). (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73; RX3869 (Cote Expert Report) ¶ 146.)

Response to Finding No. 399

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, mischaracterizes the evidence, relies on inappropriate expert opinion, and is unsupported and misleading. The proposed finding mischaracterizes Dr. Ofman's testimony. In the cited portion of the trial transcript, Dr. Ofman did not state that participants were over the age of 50, he did not state that participants were divided into different cohorts, and he did not attempt to describe the difference between cohorts. The proposed finding also mischaracterizes RX0744. Nowhere on the page cited does RX0744 state that participants were divided into different cohorts and, accordingly, no description of different cohorts is provided.

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. Dr. Cote has no personal knowledge of PATHFINDER's recruitment process. The Court should disregard this evidence. Other than the fact that PATHFINDER involved 6,662 over the age of 50, the rest of the proposed finding is unsupported by any valid evidence in the record.

The proposed finding is also misleading and incorrect to the extent it suggests that participants were first recruited into PATHFINDER and subsequently divided into different risk cohorts. In fact, Grail specifically targeted elevated risk participants for the study "to enrich the study population for the number of cancer diagnoses." (*See* RX0611 (Grail) at 31 (PATHFINDER Clinical Study Protocol). Therefore, this Court should disregard the proposed finding.

399.1 Heightened cancer risk was based on a history of smoking, genetic cancer predisposition, or a personal history of malignancy more than 5 years previously. (RX0611 (GRAIL) at 30–31.) [redacted]

Response to Finding No. 399.1

[redacted]

[redacted]

400. In February 2021, GRAIL released interim PATHFINDER results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr. 3293; [redacted]

Response to Finding No. 400

[redacted]

[redacted]

[redacted]

[redacted]

401. [redacted]

Response to Finding No. 401

[redacted]

[redacted]

402. At the time of trial, GRAIL expected to complete the PATHFINDER study in January 2022. (RX3044 (GRAIL) at 2; RX3869 (Cote Expert Report) ¶ 147.)

Response to Finding No. 402

Complaint Counsel does not disagree with the proposed finding.

c. STRIVE

403. STRIVE is a prospective, observational, longitudinal, cohort study of approximately 100,000 women undergoing mammography for screening indications and associated medical care, whose samples were taken around the time of a screening mammogram

appointment. (Cote Tr. 3804; Ofman (GRAIL) Tr. 3293–95; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.)

Response to Finding No. 403

The proposed finding is vague and incomplete. The proposed finding is vague because the terms "approximately," "for screening indications," "associated medical care," and "around the time" are undefined. The actual number of participants enrolled in STRIVE based on data from ClinicalTrials.gov is less than 99,481. (*See* PX0390 ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021). Therefore, this Court should disregard the proposed finding.

404. The goals of the STRIVE study are to confirm the performance of Galleri in a population with no known active cancer diagnosis, validate Galleri's ability to detect breast cancer and to evaluate Galleri's test performance and sensitivity in the clinically meaningful subgroup of breast cancer patients. (Ofman (GRAIL) Tr. 3293–95; Cote Tr. 3804–05; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.)

Response to Finding No. 404

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague and confusing. The proposed finding is vague because the terms "[t]he goals," "confirm," "performance," "validate," "ability to detect," "test performance and sensitivity," "clinically meaningful subgroup," and "breast cancer patients" are undefined. The proposed finding is confusing because it references both a "population with no known active cancer diagnosis" and breast cancer "patients." It is unclear how an individual can both have no active cancer diagnosis and yet simultaneously be a cancer "patient," and so it is unclear whether Respondents (Dr. Cote) are referencing one or two different groups.

The proposed finding is misleading to the extent that the references to "confirm[ing]" Galleri's performance and "validat[ing]" Galleri's ability suggest that Grail has already demonstrated a clinically meaningfully ability to detect early-stage instances of breast cancer. Complaint Counsel notes, for completeness, that Galleri detected only 7 out of 265 instances of

Stage I breast cancer in the CCGA-3 substudy (2.6%), and 93 out of 446 instances of breast cancer across Stages I-II (20.9%). Therefore, this Court should disregard the proposed finding.

405. The STRIVE study took its first sample in February 2017 and finished enrollment in November 2018. (RX0744 (GRAIL) at slide 71; RX3869 (Cote Expert Report) ¶ 148.)

Response to Finding No. 405

Complaint Counsel has no specific response to this proposed finding.

406. The STRIVE study is actively following up on the participants from their first blood draw until the first documented invasive cancer diagnosis (assessed up to 30 months), collecting data on cancer diagnosis and treatment. (RX3134 (GRAIL) at 1–2; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.)

Response to Finding No. 406

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, mischaracterizes the evidence, and relies on improper expert opinion. The proposed finding is thus also unsupported by valid record evidence. The proposed finding is vague because no timeline or reference is provided for the phrase "is actively." The proposed finding mischaracterizes RX3134. Nowhere on the cited pages does the source say that Grail (or "the STRIVE study") is "actively following up on the participants;" there is no mention of anything being "assessed up to 30 months," nor is there any mention of data collection related to "treatment" received by participants who receive a cancer diagnosis. The proposed finding also mischaracterizes RX0744. RX0744 summarizes "study objectives" and the "study design" of STRIVE, but does not comment in any way on the status of the study or suggest that Grail (or "the STRIVE study") is "actively following up on the participants."

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. Dr. Cote has no personal knowledge of the status of the STRIVE study. The Court should disregard this evidence and the proposed finding.

d. SUMMIT

407. SUMMIT is a prospective, observational, cohort study. (RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 46–47, 72; RX3869 (Cote Expert Report) ¶ 149.)

Response to Finding No. 407

Complaint Counsel does not disagree with the proposed finding.

408. The primary objective of SUMMIT is to evaluate Galleri's performance in a smoking population, meaning those with a high risk of lung cancer, with no known active cancer diagnosis. (RX3135 (GRAIL) at 1–2; RX0744 (GRAIL) at slide 72; RX3869 (Cote Expert Report) ¶ 149.)

Response to Finding No. 408

Complaint Counsel does not disagree that one of the primary objectives of SUMMIT is to assess Galleri's performance in a smoking population. The proposed finding is incomplete and misleading, however, in that Grail lists two "primary" objectives for SUMMIT, including "to examine the performance and patient experience with [low-dose CT]." RX0744 (GRAIL) at slide 72. *See* RX3135 (GRAIL) at 1 for definition of LDCT.

409. SUMMIT enrolled approximately 13,000 participants between the ages of 50–77 with a substantial smoking history exclusively from the United Kingdom. (RX3291 (GRAIL) at 1; RX3135 (Clinicaltrials.gov) at 1–2; RX3869 (Cote Expert Report) ¶ 149.)

Response to Finding No. 409

Complaint Counsel has no specific response to the proposed finding.

410. SUMMIT enrolled its first patient in April of 2019 and completed enrollment in May 2021. (RX3135 (GRAIL) at 2; RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 72; RX3869 (Cote Expert Report) ¶ 149.)

Response to Finding No. 410

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, mischaracterizes the cited evidence, relies on improper expert opinion, and is therefore unsupported. Neither RX3135 at 2, RX3291 at 1, nor RX0744 at 72 state any information about completion of enrollment for SUMMIT.

The only other source cited for the proposed finding is the actual source from which the proposed finding was copied and pasted verbatim – namely, the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. Dr. Cote has no personal knowledge of the status of the STRIVE study. The Court should disregard this evidence and the proposed finding.

411. Participants in SUMMIT will provide annual blood draws for three years, rather than a one-time blood draw. (RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 72; RX3869 (Cote Expert Report) ¶ 149.)

Response to Finding No. 411

Complaint Counsel has no specific response to the proposed finding.

412. The study intends to follow up with each participant through medical records and the National Cancer Registry for a period of 10 years. (RX0744 (GRAIL) at 72; RX3869 (Cote Expert Report) ¶ 149).

Response to Finding No. 412

Complaint Counsel has no specific response to the proposed finding.

B. Other Test Developers Alleged by Complaint Counsel To Be in the Cancer Screening Space

413. Other companies, including Exact Sciences Corp. ('Exact'), Thrive Earlier Detection Corp. ('Thrive'), Guardant, Inc. ('Guardant'), Singlera Genomics, Inc. ('Singlera'), Freenome, Inc. ('Freenome'), Helio Health, Inc. ('Helio'), Natera, Inc. ('Natera'), and Foundation Medicine ('FMI'), are or purport to be developing cancer screening tests. These companies are all far behind GRAIL in the development of a multi-cancer screening test.

Response to Finding No. 413

The proposed finding is unsupported and vague because no evidence is cited. This Court should disregard the proposed finding. The proposed finding is also vague because the term "far behind" is undefined. Therefore, this Court should disregard the proposed finding.

1. Exact Sciences / Thrive Earlier Detection

414. Exact Sciences Corp. ("Exact") is a molecular diagnostics company based in Madison, Wisconsin. (RX3197 (Exact/Thrive) at 1, 4.) Thrive Earlier Detection Corp. ("Thrive"), now a part of Exact, is a molecular diagnostics company based in Cambridge, Massachusetts and Baltimore, Maryland. (RX2650 (Morgan Stanley) at 4.)

Response to Finding No. 414

Complaint Counsel does not disagree with the proposed finding.

415. Thrive was founded in 2019 by licensing technologies developed at the Johns Hopkins University by founding professors Bert Vogelstein, Kenneth W. Kinzler, and Nickolas Papadopoulos. (RX3398 (Johns Hopkins Technical Ventures) at 2; RX3869 (Cote Expert Report) ¶ 173.)

Response to Finding No. 415

Complaint Counsel does not disagree with the proposed finding.

416. While Thrive was founded in 2019, it builds on research from the Vogelstein group and from Vogelstein's efforts in his prior company, PapGene, which was founded in 2014. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 26–29); RX3869 (Cote Expert Report) at ¶ 173.)

Response to Finding No. 416

The proposed finding is vague because it does not define the terms "builds on research" or "efforts in his prior company." Additionally, the proposed finding is unsupported by the cited exhibits. To the extent the proposed finding is based on Dr. Cote's Expert Report, Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

417. Exact/Thrive is currently developing a cancer screening test known as "CancerSEEK". (Lengauer (Exact/Thrive) Tr. 158.)

Response to Finding No. 417

Complaint Counsel does not disagree with the proposed finding.

418. Complaint Counsel has presented no evidence that the current version of CancerSEEK in development is capable of competing with the Galleri test unless significant changes are made to the assay. (Cote Tr. 3814–15, 3823; RX3869 (Cote Expert Report) ¶ 174.)

Response to Finding No. 418

This Court ordered that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here, Respondents cite Dr. Cote as the only source of evidence supporting the proposed fact in contravention of this Court's Order. This Court should disregard this evidence.

[redacted]

[redacted]

[redacted] This Court should not accord Dr. Cote's opinion[s] any weight. Therefore, this Court should disregard the proposed finding.

419. Specifically, the CancerSEEK assay is only designed to detect 10 cancer types, not the over 50 types of cancers by Galleri. (RX3869 (Cote Expert Report) ¶ 174.) Also, the CancerSEEK assay does not identify the cancer signal of origin, which is why it is combined with a whole-body PET-CT. (RX3869 (Cote Expert Report) ¶ 174.)

Response to Finding No. 419

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is improper, unreliable, misleading, and against the weight of evidence. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report as support for both sentences, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 174; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Cote's expert opinions to support this portion of the proposed finding, in contravention of this Court's Order, and therefore this Court should disregard the Respondents' proposed finding.

The proposed finding is also misleading and against the weight of evidence to the extent that it suggests there is evidence that Galleri can provide early detection of more cancers than CancerSEEK in a screening population. Just the opposite is in fact the case. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population.

[redacted]

[redacted]

Respondents' reference to "over 50 cancer types" is misleading because it seeks to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. [redacted] Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

[redacted]

[redacted]

420. [redacted]

Response to Finding No. 420

[redacted]

[redacted]

[redacted]

[redacted]

421. [redacted]

Response to Finding No. 421

[redacted]

[redacted]

[redacted]

a. Exact/Thrive's CancerSEEK Test

422. CancerSEEK is a multiomics test. (RX3869 (Cote Expert Report) ¶ 174.) The reported version of CancerSEEK requires several steps. (RX3419 (Lennon et al., 2020); Lengauer (Exact/Thrive) Tr. 246–48, 260.)

[redacted]

Response to Finding No. 422

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is improper, unreliable, misleading, and vague. The proposed finding violates this Court's Post-Trial Order in three different ways: (1) it improperly cites expert opinion to support

a factual proposition, (2) it fails to provide any specific page reference to a cited source, and (3) it improperly includes (and cites by reference) a demonstrative not in evidence.

Respondents cite only to Dr. Cote's report to support the first sentence of the proposed finding. This is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Respondents' proposed citation thus contravenes this Court's Order. This Court should disregard this evidence.

Second, Respondents' fail to provide the page number for their proffered citation to RX3419. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3419 is a 43-page document; Respondents fail to cite any specific page or page range in the document in contravention of the Court's Order. The Court should also disregard this proposed evidence.

Third, Respondents include an improper demonstrative in their proposed finding. This Court ordered that no Party shall cite to evidence that was determined at trial to be "disregarded" or "not considered" or otherwise not in evidence. *See* Order on Post-Trial Findings at 3. This Court should disregard this evidence. *See* Chicago Bridge & Iron Co., Dkt 9300. *See* 2003 FTC LEXIS 98 (June 12, 2003) (striking unadmitted exhibits cited in findings of fact). Here Respondents reproduce RDX0014-57 in contravention of this Court's Order. The material in RDX0014-57 is uncited, meaning the only citation provided by Respondents is the RDX number itself. The inclusion of this improper demonstrative is itself misleading because Respondents' use of the Thrive logo at the top of the document suggests that it is an actual Thrive document, when in fact it is a non-evidentiary demonstrative exhibit created by Respondents. The Court

should disregard this proposed evidence and thus the proposed finding.

423. The first iteration of the CancerSEEK blood test analyzed two types of biomarkers: 16 gene mutations and nine protein biomarkers (including 61 variant regions of interest within the genes, called "amplicons"). (Lengauer (Exact/Thrive) Tr. 210–11; RX3419 (Lennon et al., 2020) at 3.)

Response to Finding No. 423

Complaint Counsel does not disagree with the proposed finding.

424. In the DETECT-A clinical trial, two blood tests were performed in the Thrive workflow. (Lengauer (Exact/Thrive) Tr. 247; RX3419 (Lennon et al., 2020) at 3.)

Response to Finding No. 424

Complaint Counsel does not disagree with the proposed finding.

424.1 Initially, a baseline CancerSEEK test was performed and then an additional confirmatory blood test was performed on the individuals who tested positive for cancer to assess only the particular DNA or protein markers that were abnormal in the baseline, as well as to rule out the presence of clonal hematopiesis (CHiP), which is a blood mutation that might cause false positives in those DNA or protein markers. (Lengauer (Exact/Thrive) Tr. 247; [redacted]; RX3419 (Lennon et al., 2020) at 3).)

Response to Finding No. 424.1

Complaint Counsel does not disagree with the proposed finding.

425. Individuals remaining positive after the two blood tests were then scanned using full-body PET-CT imaging. (Lengauer (Exact/Thrive) Tr. 248; Cote Tr. 3811–12; [redacted] RX3419 (Lennon et al., 2020) at 3.)

Response to Finding No. 425

Complaint Counsel has no specific response to the proposed finding.

425.1 The CancerSEEK assay as it exists today is not a liquid biopsy-only test, and does not solely rely on NGS. (RX3869 (Cote Expert Report) ¶ 175.)

Response to Finding No. 425.1

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is improper, unreliable, vague, misleading, and against the weight of evidence.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report and testimony in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 175; *see* Order on Post-Trial Findings at 3). This Court should disregard the Respondents' proposed finding.

The proposed finding is vague because the terms "CancerSEEK assay," "as it exists today" and "liquid biopsy-only test" are undefined. Respondents cite no documentary or testimonial evidence for the proposition that the CancerSEEK *assay* itself is "not a liquid biopsy-only test," whatever that term means.

The proposed finding is also misleading to the extent it suggests that Galleri is a "liquid biopsy-only test" in a way that CancerSEEK is not. [redacted] Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

[redacted] If Grail had already established the extent to which PET-CT and other types of diagnostic testing would be required to achieve diagnostic resolution when Galleri is used in a real-world setting, such a study would not be necessary. Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). Therefore, this Court should disregard the

proposed finding.

426. [redacted]

Response to Finding No. 426

[redacted]

[redacted]

426.1 In the earlier case-control study conducted by Thrive's founders, CancerSEEK was able to localize the cancer signal of origin to two anatomic sites in a median of 83% of patients. (RX3142 (Cohen 2018) at 3.)

Response to Finding No. 426.1

[redacted]

426.2 However, this method was not used in the DETECT-A study, where Thrive opted for a full-body PET-CT instead. (Lengauer (Exact/Thrive) Tr. 248; RX3869 (Cote Expert Report) at n. 240.)

Response to Finding No. 426.2

The proposed finding is vague and confusing because the term "this method" is undefined. Therefore, this Court should disregard the proposed finding.

426.3 Of the 53 patients identified by PET-CT as having "imaging concerning for cancer," only 15 was determined to have cancer, with only a 28.3% detection rate. (RX3419 (Lennon et al., 2020) at 4, Fig. 2; Lengauer (Exact/Thrive) Tr. 255–56.)

Response to Finding No. 426.3

The proposed finding, which consists of language copied and pasted nearly verbatim from footnote 240 of Dr. Cote's report, is vague, unsupported, misleading, and unreliable. The proposed finding is vague because the term "identified by PET-CT" is vague and no context is given for how PET-CT was specifically used in the study design. The term "detection rate" is also vague, undefined, and appears nowhere in the material source. The proposed finding is unsupported because page 4 of RX3419 fails to support any of the statements in the proposed finding. To the extent Respondents intended to cite to Figure 2 on page 5 of RX3419, that figure also does not state that 15 of 53 patients identified by PET-CT as having imaging concern for cancer were determined to have cancer, or make any reference to a "28.3% detection rate."

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted nearly verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 175 n.240), even though Respondents do not attribute it to Dr. Cote. Respondents copy-and-paste was only *nearly* verbatim. Respondents changed two of the numbers from n.240 of Dr. Cote's report. Dr. Cote refers to "the 54 patients identified by PET-CT" (versus "the 53 patients identified by PET-CT" referenced in this finding) and a "27.8% detection rate" (versus the "28.3% detection rate" referenced in this finding). The source of the

proposed finding appears to be a calculation of some sort performed by Dr. Cote using numbers derived from a source other than the specific page and Figure cited. Respondents themselves apparently believe that Dr. Cote used inaccurate numbers for that calculation because Respondents changed Dr. Cote's numbers for purposes of this finding. The finding is inherently unreliable and should be disregarded.

> 426.4 Full-body PET-CT is a fairly poor tool for cancer signal of origin determination, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (RX3869 (Cote Expert Report) at n. 240.)

Response to Finding No. 426.4

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's expert report, is vague, misleading, unsupported, and unreliable. The proposed finding is vague because the term "fairly poor" is undefined.

The proposed finding is also misleading because the actual sentence in Dr. Cote's report begins: "*Therefore*, full-body PET-CT is a fairly poor tool . . . ." (RX3869 (Cote Expert Report) at n. 240 (emphasis added)). Dr. Cote is referencing the previous sentence from footnote 240 of his report, which Respondents pasted in (nearly) verbatim as Proposed Finding No. 426.3. As noted in Complaint Counsel's response to Respondents' Proposed Finding No. 426.3, that finding is unsupported, misleading, and inherently unreliable because Respondents pasted Dr. Cote's language into the finding while changing the specific numbers from his report. Respondents then misleadingly attributed the (changed) calculation to the authors themselves (Lennon et al.) rather than to Dr. Cote. (*See* Response to RPFF ¶ 426.3 above).

No citation is provided for the "88.7% accuracy" number included in the proposed citation; that portion of the proposed finding is unsupported. [redacted]

[redacted]

[redacted] Any attempt to compare Galleri's CSO performance in CCGA against PET-CT's performance in a study that *did* involve an asymptomatic screening population, that *included* false positives when assessing PET-CT performance, and that *only* included predictions as correct when they were actually correct is inherently unreliable and misleading.

Moreover, even setting aside the numerous issues noted above, Dr. Cote is not even purporting to compare apples-to-apples. He is comparing a "detection rate" to an "accuracy" figure. Such a comparison is irrelevant and has no probative value. Certainly, it has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This finding should be accorded no weight by this court.

[redacted] Further, Dr. Cote is neither a board-certified medical oncologist nor a primary care physician, as such it is not within his job to order workup for patients who have tested positive for cancer. (Cote, Tr. 3978-79). [redacted]

427. To date, CancerSEEK has been studied in two trials: Cohen, a case-control study conducted by Thrive's founders at Johns Hopkins University involving 1817 participants (1005 cancer patients and 812 healthy individuals), and Lennon, the prospective, interventional DETECT-A (Detecting cancers Earlier Through Elective mutation-based blood Collection and Testing) study conducted by Thrive involving 10,006 female participants. (RX3142 (Cohen 2018) at 1; RX3419 (Lennon et al., 2020) at 2); [redacted]

Response to Finding No. 427

[redacted]

428. Although all cancer types (with some exclusions) were purportedly included in the DETECT-A study, in fact the nature of the assay (focusing on 16 genes and 9 protein biomarkers) was such that it was clearly designed to focus on only a few cancers that might be detected in a liquid biopsy screening test using those limited markers. (RX3419 (Lennon et al., 2020) at 2–4.)

Response to Finding No. 428

The proposed finding is vague, misleading, mischaracterizes the evidence, and is unsupported and improper. The proposed finding is vague because the terms "all cancer types (with some exclusions)," "nature of the assay," "clearly designed," and "only a few" are ambiguous and undefined.

[redacted]. Respondents mischaracterize RX3419. The authors of RX3419 say nothing about the assay being "clearly designed to focus on only a few cancers," "limited markers," or anything similar. The proposed finding is improper, unreliable, unsupported, and should be accorded no weight.

429. The study only detected cancers of 10 organs: lymphoma, colorectal, appendix, uterine, thyroid, kidney, lung, breast, ovary and cancer of unknown primary. (RX3419 (Lennon et al., 2020) at 4, 6–7, 9; Lengauer (Exact/Thrive) Tr. 243, 260–61.)

Response to Finding No. 429

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 177), even though Respondents do not attribute it to Dr. Cote.

[redacted]. In fact, the opposite is the case. Galleri has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021) (showing seven cancers as being detected in Stages I-III: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine); *see also* Cote Tr. 4000-01). By comparison, Thrive's CancerSEEK test has been shown to detect eight types of Stage I-III cancer in an asymptomatic screening population. (*See* RX3419 (Lennon et al., Feasibility of Blood Testing

Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020) at 6-7, Table 1) (showing eight cancers as being detected in Stages I-III: ovary, lung, uterine, thyroid, colorectal, breast, lymphoma, and kidney). Therefore, this Court should disregard the proposed finding.

> 429.1 Based on these results and the assay design itself, the evidence does not support the proposition that CancerSEEK currently detects the same number of cancer types as GRAIL's Galleri test. (RX3869 (Cote Expert Report) ¶ 177.)

Response to Finding No. 429.1

The proposed finding is vague and misleading. The proposed finding is vague because the terms "these results," "the assay design itself," and "the evidence" are undefined and ambiguous.

The proposed finding is also misleading to the extent that it is meant to suggest that CancerSEEK is capable of detecting fewer cancers early in a screening setting than Grail. In fact, the opposite is the case. Galleri has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021) (showing seven cancers as being detected in Stages I-III: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine); *see also* Cote Tr. 4000-01). By comparison, Thrive's CancerSEEK test has been shown to detect eight types of Stage I-III cancer in an asymptomatic screening population. (*See* RX3419 (Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020) at 6-7, Table 1) (showing eight cancers as being detected in Stages I-III: ovary, lung, uterine, thyroid, colorectal, breast, lymphoma, and kidney).

Any attempt to compare the number of cancers "detected" in DETECT-A (an interventional study involving asymptomatic individuals) with CCGA (a case-control study

involving diagnosed cancer patients, including patients with Stage IV cancer) is misleading and unreliable. They are fundamentally different types of studies. Dr. Ofman of Grail conceded that "[t]o find all 50 cancer types in a real-world population would require hundreds of thousands of people[.]" (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). [redacted] (*See, e.g.,* RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms"); CCFF ¶ 640 [redacted] The fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population. [redacted] In their own proposed findings of fact, Respondents admit that "for an early cancer screening test, whose target population comprises asymptomatic individuals who do not have a diagnosis of cancer, the clinical study cannot use samples from cancer patients" if it is to represent "valid scientific evidence used to determine the effectiveness of a device." (*See* RPFF ¶¶ 319-320). Therefore, this Court should disregard the proposed finding.

430. [redacted]

Response to Finding No. 430

[redacted]

[redacted]

430.1 CancerSEEK is unable to detect several cancers that Galleri has detected. (*Compare* RX3419 (Lennon et al., 2020) at 1, 6–7, 9 *with* (RX3409 (Klein et al., 2021) at 1, 5; Cote Tr. 3818–19.)

[redacted]

Response to Finding No. 430.1

The proposed finding is vague, misleading, unsupported, and violates the Court's Post-Trial Order. The proposed finding is vague because the phrases "unable to detect" and "has detected" are vague and undefined.

The proposed finding is misleading because any attempt to compare the number of cancers "detected" in DETECT-A (an interventional study involving asymptomatic individuals) with CCGA (a case-control study involving diagnosed cancer patients, including patients with Stage IV cancer) is misleading and unreliable. They are fundamentally different types of studies. Dr. Ofman of Grail conceded that "[t]o find all 50 cancer types in a real-world population would require hundreds of thousands of people[.]" (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298).

[redacted]

(*See, e.g.,* RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms"); [redacted] The fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population. [redacted]

[redacted]

[redacted] In their own proposed findings of fact, Respondents admit that "for an early cancer screening test, whose target population comprises asymptomatic individuals who do not have a diagnosis of cancer, the clinical study cannot use samples from cancer patients" if it is to represent "valid scientific evidence used to determine the effectiveness of a device." (*See* RPFF ¶¶ 319-320).

[redacted]

The proposed finding also includes an improper demonstrative. This Court ordered that no Party shall cite to evidence that was determined at trial to be "disregarded" or "not considered" or otherwise not in evidence. Here Respondents reproduce RDX0014-51 in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The specific image presented in the demonstrative does not appear in the sources cited, meaning the only citation provided by Respondents for the figure is the RDX number itself. This Court should disregard this evidence. *See* Chicago Bridge & Iron Co., Dkt 9300. *See* 2003 FTC LEXIS 98 (June 12, 2003) (striking unadmitted exhibits cited in findings of fact). The inclusion of the figure is itself misleading because it incorrectly suggests that the image presented is from the sources cited in the proposed finding. Therefore, this Court should disregard the proposed finding.

431. In the DETECT-A study, CancerSEEK obtained specificities of 95.3% in its baseline blood test (that is, with a single blood test), 98.9% with both baseline and confirmational blood tests (two blood tests) *without* PET-CT imaging, and 99.6% with both blood tests and PET-CT imaging, and sensitivity of 30.2% in its baseline blood test, 27.1% with

both baseline and confirmational blood tests *without* PET-CT imaging, and 15.6% with both blood tests and PET-CT imaging. (RX3419 (Lennon et al., 2020) at 8 & Table 2.)

Response to Finding No. 431

Complaint Counsel does not disagree with the proposed finding.

432. Assessed using another test benchmark, CancerSEEK obtained PPV (positive predictive value) of 5.9% with its single baseline blood test, 19.4% with baseline and confirmational blood tests *without* PET-CT imaging, and 28.3% with both blood tests and PET-CT imaging. (RX3419 (Lennon et al., 2020) at 8 & Table 2; Lengauer (Exact/Thrive) Tr. 257–59; RX3869 (Cote Expert Report) ¶ 178.)

Response to Finding No. 432

The proposed finding is vague because the term "another test benchmark" is vague and undefined. Complaint Counsel does not disagree that the factual statistics presented correspond with the statistics reported in Table 2 of RX3419.

433. [redacted]

Response to Finding No. 433

Complaint Counsel does not disagree with the proposed finding.

434. [redacted]

Response to Finding No. 434

The proposed finding is vague because it does not define the term "support the PMA application." Therefore, this Court should disregard the proposed finding.

434.1 [redacted]

[redacted]

Response to Finding No. 434.1

[redacted]

435. [redacted]

Response to Finding No. 435

The proposed finding is vague because it does not define the terms "under evaluation," "could be important," or "recognized." In addition, Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)). Therefore, this Court should disregard the proposed finding.

436. [redacted]

[redacted]

Response to Finding No. 436

The proposed finding is confusing because it contains two separate, unrelated statements. The proposed finding is also vague because it does not define the term "committed." [redacted]

437. [redacted]

Response to Finding No. 437

Complaint Counsel does not disagree with the proposed finding.

438. [redacted]

Response to Finding No. 438

[redacted]

[redacted]

438.1 The inability of CancerSEEK to identify the cancer signal of origin through liquid biopsy alone is a key differentiator and means that if CancerSEEK were to launch today in its current form, it is unlikely to be a close substitute for GRAIL's Galleri test. (Cote Tr. 3814; PX6097 (Abrams Expert Report) ¶ 38.)

Response to Finding No. 438.1

The proposed finding is vague, mischaracterizes the cited evidence, is unsupported, relies on improper expert opinion, and is misleading and against the weight of evidence. The proposed finding is vague because the terms "cancer signal of origin" "key differentiator," and "close substitute" are undefined. The term "cancer signal of origin is not generally used by companies other than Grail.

The proposed finding mischaracterizes the cited evidence. Neither Dr. Cote nor Dr. Abrams refers to the presence or absence of "cancer signal of origin through liquid biopsy alone" as a "key differentiator" and neither opines on whether CancerSEEK would be a "close substitute" for Galleri in the citations referenced. The proposed finding is thus unsupported. Additionally, neither Drs Cote nor Abrams are qualified to provide expert opinion about whether other MCED tests will compete in the same market with the Galleri test because neither is an economist. (*See* Response to RPFF ¶ 1959, above (examining Dr. Cote's lack of qualifications on subject of market definition)). Dr. Abrams is also too biased and unqualified to opine on

whether or how the decision-making of physicians besides himself will be impacted by tests providing accurate cancer signal of origin. (*See* Response to RPFF ¶ 2032, below (examining Dr. Abrams's bias towards Grail and his lack of qualifications on how other physicians besides himself will make decisions regarding Galleri and other MCED tests)).

The proposed finding is also misleading to the extent it suggests that Galleri's algorithmic cancer signal of origin prediction is capable of definitively localizing cancer "through liquid biopsy alone." Reliable clinical data does not exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population. The Galleri CSO accuracy numbers reported in CCGA-3 do not indicate the likelihood that a particular CSO prediction accurately identifies the location of an individual's' cancer because (1) CCGA did not involve an asymptomatic screening population, (2) the study excluded false positives when assessing CSO accuracy, and (3) Grail counts Galleri's CSO predictions as "correct" *even in instances when Galleri does not actually identify the location of the underlying cancer*. (*See* Complaint Counsel's Post-Trial Reply Brief at 50-54). Additionally, a positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (*e.g.* imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.)

Interim results from PATHFINDER, an actual interventional trial for Galleri, indicate that additional imaging testing was required for positive results 90 percent of the time. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting

Presentation, June 4, 2021) ("Most participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)."). Over half the positive results in PATHFINDER with diagnostic resolution were determined to be false positives (55.4%) and 25 percent of participants who received falsely positive results underwent at least one invasive procedure. (RX3041 at 004 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

[redacted]

438.2 [redacted]

Response to Finding No. 438.2

[redacted]

[redacted]

439. [redacted]

[redacted]

Response to Finding No. 439

[redacted]

[redacted]

439.1 [redacted]

[redacted]

Response to Finding No. 439.1

[redacted]

[redacted]

440. [redacted]

Response to Finding No. 440

[redacted]

[redacted]

441. [redacted] (Conroy (Exact/Thrive) Tr. 1709, 1717; [redacted]

Response to Finding No. 441

[redacted]

[redacted]

[redacted]

442. [redacted]

[redacted]

Response to Finding No. 442

[redacted]

[redacted]

[redacted]

443. [redacted]

Response to Finding No. 443

[redacted]

[redacted]

2. FMI / Roche

444. Foundation Medicine, Inc. ("FMI") is a subsidiary of the Roche Group based in Cambridge, Massachusetts. (RX3869 (Cote Expert Report) ¶ 184.) [redacted]

Response to Finding No. 444

[redacted]

[redacted]

445. [redacted]

Response to Finding No. 445

[redacted]

a. [redacted]

446. [redacted]; PX7068 (Perettie (FMI) IHT at 68); RX3869 (Cote Expert Report) ¶ 185.)

[redacted]

Response to Finding No. 446

[redacted]

[redacted]

[redacted]

447. [redacted]
PX7068 (Perettie, IHT at 57, 59).) [redacted]

Response to Finding No. 447

[redacted]

448. [redacted]

Response to Finding No. 448

[redacted]

448.1 [redacted]

Response to Finding No. 448.1

448.2

Response to Finding No. 448.2

449.

Response to Finding No. 449

[redacted]

450. [redacted]

Response to Finding No. 450

[redacted]

[redacted]

451. [redacted]

[redacted]

[redacted]

[redacted]

Response to Finding No. 451

[redacted]

[redacted]

452. [redacted]

Response to Finding No. 452

[redacted]

453. FMI and Roche currently do not have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 189.)

Response to Finding No. 453

The proposed finding, which consists of language copied and pasted from Dr. Cote's report, is vague and relies on improper expert opinion in contravention of this Court's Order. The proposed finding is vague because the terms "currently" and "relating to" are undefined.

The proposed finding also relies solely on improper expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

b. [redacted] Other Oncology Test Development Efforts

454. [redacted]

Response to Finding No. 454

Complaint Counsel has no specific response to this proposed finding.

455. [redacted]

Response to Finding No. 455

[redacted]

[redacted]

3. Freenome

456. Freenome is a biotechnology company based in South San Francisco, California. [redacted] Freenome was started in 2014 and has been working on its colorectal cancer early detection test since that time. (Nolan (Freenome) Tr. 2724, [redacted]

Response to Finding No. 456

Complaint Counsel has no specific response to this proposed finding.

457. Freenome commenced development of its multiomics platform (which it intends to use for cancer screening) in 2016. [redacted] at 13, [redacted]).) Freenome has published data only relating to a single cancer, colorectal, and has commenced additional clinical trials only relating to colorectal cancer screening. (RX3869 (Cote Expert Report) ¶ 192; [redacted]

Response to Finding No. 457

[redacted]

458. There is no indication based on Freenome's work to date that Freenome will be a competitor to GRAIL in the foreseeable future, and depending on the test that Freenome

develops in the future, it is unclear if it will be a competitor to GRAIL or will develop a complementary test. [redacted] RX3869 (Cote Expert Report) ¶ 193.)

Response to Finding No. 458

[redacted]

[redacted]

a. [redacted]

459. [redacted] However, Dr. Scott Morton has not presented evidence supporting this contention, and there is none. [redacted]

[redacted]

Response to Finding No. 459

[redacted]

[redacted]

460. The former CEO of Freenome, Gabriel Otte, testified that Freenome is developing a "multiomics cancer screening assay" and is currently "in the process of assessing the clinical

performance of the CRC [*i.e.*, colorectal] portion of that test." (PX7121 (Otte (Freenome) Dep. at 16).)

Response to Finding No. 460

461.

RX3869 (Cote Expert Report) ¶ 194.)

Response to Finding No. 461

[redacted]

462. [redacted]

Response to Finding No. 462

[redacted]

[redacted]

463. [redacted]

Response to Finding No. 463

[redacted]

[redacted]

[redacted]

[redacted]

464. [redacted]

Response to Finding No. 464

[redacted]

[redacted]

[redacted]

[redacted]

464.1 [redacted]

Response to Finding No. 464.1

[redacted]

[redacted]

465. [redacted]

Response to Finding No. 465

[redacted]

[redacted]

466. [redacted]

Response to Finding No. 466

[redacted]

467. [redacted]

Response to Finding No. 467

[redacted]

[redacted]

[redacted]

468. [redacted]

Response to Finding No. 468

[redacted]

[redacted]

469. [redacted]

Response to Finding No. 469

[redacted]

470. [redacted]

Response to Finding No. 470

[redacted]

[redacted]

b. Freenome's Colorectal Cancer Screening Test

471. Freenome is currently developing a blood biopsy colorectal cancer screening test by combines data from whole-genome sequencing, DNA methylation, and protein quantification using a multiomics approach. (RX3426 (Lin et al., 2021); RX3592 (Putcha et al., 2020).) Freenome is able to achieve single cancer specificity of 94% with sensitivity of 91% using this multiomics approach. (RX3869 (Cote Expert Report) ¶ 199.)

Response to Finding No. 471

The proposed finding relies on improper expert opinion. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the fact that "Freenome is able to achieve single cancer specificity of 94% with sensitivity of 91% using this multiomics approach" in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

472. Freenome is currently conducting a 14,000–participant, prospective, observational cohort study to validate its blood-based multiomics test for the early detection of colorectal cancer. (RX3132 (Freenome).) [redacted]

Response to Finding No. 472

Complaint Counsel objects to Respondents' misattribution of RX3132 (which appears to be an internet printout Respondents generated in July of 2021 from clinicaltrials.gov) to Freenome as the source of the document in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Therefore, this Court should disregard the proposed finding.

4. Guardant Health

473. Guardant Health ("Guardant") is a molecular diagnostics company based in Redwood City, California. (RX3472 (Guardant) at 4.) Guardant was founded in 2011, and launched its first product, a therapy selection test around the same time. (RX3472 (Guardant) at

4; PX7045 (Chudova (Guardant) IHT at 17).) [redacted]

Response to Finding No. 473

Complaint Counsel objects to Respondents' misattribution of RX3472 (which Respondents note on JX2 is, in fact, a printout from www.nasdaq.com) to Guardant as the source of the document in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Therefore, this Court should disregard the proposed finding.

474. [redacted]

Response to Finding No. 474

[redacted]

475. [redacted]

[redacted]

Response to Finding No. 475

[redacted]

[redacted]

[redacted]

a. [redacted]

476. There is no evidence that that Guardant will launch in the foreseeable future a cancer screening test that is a close substitute to the Galleri test. (RX3869 (Cote Expert Report) ¶ 203.)

Response to Finding No. 476

[redacted]

[redacted]

[redacted]

477. [redacted]; PX7045 (Chudova (Guardant) IHT at 19); RX3869 (Cote Expert Report) ¶ 203).

[redacted]

Response to Finding No. 477

[redacted]

[redacted]

478. [redacted]

Response to Finding No. 478

[redacted]

[redacted]

478.1 [redacted]

Response to Finding No. 478.1

[redacted]

479. [redacted]

[redacted]

Response to Finding No. 479

[redacted]

479.1 [redacted]

Response to Finding No. 479.1

[redacted]

[redacted]

479.1.1 [redacted]

Response to Finding No. 479.1.1

[redacted]

[redacted]

479.2 [redacted]

Response to Finding No. 479.2

[redacted]

[redacted]

479.2.1 [redacted]

Response to Finding No. 479.2.1

[redacted]

[redacted]

479.2.2 [redacted]

Response to Finding No. 479.2.2

[redacted]

[redacted]

479.3 [redacted]

Response to Finding No. 479.3

[redacted]

[redacted]

479.4 [redacted]

Response to Finding No. 479.4

[redacted]

[redacted]

479.4.1 [redacted]

Response to Finding No. 479.4.1

[redacted]

[redacted]

479.4.2 [redacted]

Response to Finding No. 479.4.2

[redacted]

[redacted]

479.5 [redacted]

Response to Finding No. 479.5

[redacted]

[redacted]

479.5.1 [redacted]

Response to Finding No. 479.5.1

[redacted]

480. Guardant has also testified that its "platform in its foundation doesn't have anything specific for [] individual cancer types other than selection of the regions of the genomes that are most representative for that specific cancer." (PX7100 (Chudova (Guardant) Dep. at 24).)

Response to Finding No. 480

The proposed finding is vague and incomplete. The proposed finding is vague because it refers to testimony by "Guardant," rather than to the individual testimony of Dr. Chudova. The proposed finding is also incomplete. Dr. Chudova testified that Guardant's "platform in its

foundation doesn't have anything specific for an individual cancer types other than selection of the regions of the genomes that are most representative for that specific cancer. But that's a minor aspect of the technology, and it can be adapted to other cancer types." (PX7100 (Chudova (Guardant) Dep. at 24)). Therefore, this Court should disregard the proposed finding.

481. Guardant also acknowledged that "[t]here's also [the] possibility that we would need to bring other biomarkers to support the sensitivity and specificity requirements in those other cancers, but that's an area of development at this point." (PX7100 (Chudova (Guardant) Dep. at 23–24, 26); RX3869 (Cote Expert Report) ¶ 205).

Response to Finding No. 481

The proposed finding is incomplete and misleading. [redacted]

[redacted]

482. [redacted]

Response to Finding No. 482

[redacted]

[redacted]

482.1 [redacted]
Chudova (Guardant) Tr. 1179.)

Response to Finding No. 482.1

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] Therefore, this

Court should disregard the proposed finding.

482.2 [redacted]

Response to Finding No. 482.2

[redacted]

483. [redacted]

Response to Finding No. 483

[redacted]

[redacted]

[redacted]

483.1 [redacted]

Response to Finding No. 483.1

[redacted]

[redacted]

[redacted]

484. [redacted] Dr. Scott Morton provided no basis for this, and Guardant testified that this determination is based on "internal development data" that has not been validated or published. ([redacted], 26–27); [redacted]

Response to Finding No. 484

[redacted]

[redacted]

485. In addition, Guardant currently does not have any clinical trials relating to screening for multiple cancers simultaneously listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 208.) [redacted]

[redacted]

Response to Finding No. 485

[redacted]

[redacted]

[redacted]

[redacted]

b. Guardant's LUNAR-2 Colorectal Cancer Screening Tests

486. Guardant is currently developing an NGS-based blood biopsy early cancer screening test using genomic and methylation signatures called LUNAR-2, to detect and screening for early-stage colorectal cancer. (RX3296 (Guardant) at 7.)

Response to Finding No. 486

The proposed finding is incomplete and misleading. Complaint Counsel does not disagree that Guardant is developing an NGS-based liquid biopsy early cancer screening test called LUNAR-2 that uses genomic and methylation signatures. The proposed finding is incomplete and misleading, however, to the extent it suggests that LUNAR-2 is only intended to screen for early-stage colorectal cancer. [redacted]

[redacted]

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 209), even though Respondents do not attribute it to Dr. Cote. With the exception of the specific language noted with which Complaint Counsel does not disagree, this Court should disregard the proposed finding.

> 486.1 In 2019, Guardant reported a 107–participant study with 72 patients with Stage I–IV colorectal cancer and 35 age-matched cancer-free individuals. (RX3405 (Kim et al., 2019) at 1–2.) The LUNAR-2 test was 94% sensitive at 94% specificity, with sensitivity at 97% in Stage I/II, 90% in Stage III, and 100% in stage IV. (RX3405 (Kim et al., 2019) at 2).) The authors also found that DNA methylation analysis significantly enhanced ctDNA detection relative to somatic mutational analysis alone (94% vs. 56%; $p<0.0001$). (RX3405 (Kim et al., 2019) at 2).)

Response to Finding No. 486.1

The proposed finding is misleading and mischaracterizes the source cited, which is itself

unreliable hearsay.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 209), even though Respondents do not attribute it to Dr. Cote. Rather, Respondents attempt to improperly misattribute Dr. Cote's statements to the "authors" of RX3405 (Kim et al.). Moreover, Respondents cite only to a an abstract rather than the full study and fail to disclose the specific source from which the abstract was printed. An abstract of unknown provenance that was not produced by Guardant itself is not a reliable source of what "Guardant reported."

Additionally, Respondents mischaracterize the contents of the cited abstract itself. Respondents assert that the LUNAR-2 test "was 94% sensitive at 94% specificity." In fact, the abstract states that those sensitivity and specificity numbers were for "early stage CRC (I-III)" *only*. The stated performance of the LUNAR-2 test for early stage CRC is thus superior to that implied by Respondents' inaccurate summary of the abstract (given that the sensitivity noted for Stage IV patients was 100%). The Court should thus disregard the proposed finding.

> 486.2 In 2020, Guardant reported a 205–participant study with 113 patients with stage I-III colorectal cancer and 88 age-matched colonoscopy screen-negative individuals. (RX3740 (Westesson et al., 2020) at 2); (RX3869 (Cote Expert Report) ¶ 209). The LUNAR-2 test was 90.3% sensitive at 96.6% specificity, with sensitivity at 90% in Stage I; 88% in Stage II; 96% in Stage III. (RX3740 (Westesson et al., 2020) at 2); (RX3869 (Cote Expert Report) ¶ 209.)

Response to Finding No. 486.2

The proposed finding is misleading and mischaracterizes the source cited, which is itself unreliable hearsay.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted from Dr. Cote's report (RX3869 (Cote Report) ¶

209), even though Respondents do not attribute it to Dr. Cote. Rather, Respondents attempt to improperly misattribute Dr. Cote's statements to the "authors" of RX3740 (Westesson et al.). Moreover, Respondents cite only to a an abstract rather than the full study that was apparently printed by Respondents off of the internet. An abstract that was not produced by Guardant itself is not a reliable source of what "Guardant reported."

Additionally, Respondents mischaracterize the contents of the cited abstract itself. Respondents assert that Westesson et al. involved a "205-participant study." In fact, the abstract states that "blood samples were collected from 162 patients with a known diagnosis of CRC . . ., 38 self-declared cancer-free donors, *and* 205 individuals who were screen-negative for advanced neoplasia by colonoscopy." Those numbers total to 405, not 205. Complaint Counsel does not disagree that the sensitivities and specificity listed in the proposed finding correspond to the numbers listed in the abstract, but reiterates its objection to the use of an abstract printed off the internet as evidence about what Guardant specifically reported. The Court should disregard the proposed finding.

487. In 2019, Guardant initiated the approximately 10,000–participant ECLIPSE prospective observational trial to evaluate the performance of the LUNAR-2 colorectal cancer screening test and support its submission to the FDA. (RX3128 (Guardant) at 1–2; Chudova (Guardant) Tr. 1155, [redacted] ECLIPSE is expected to complete enrollment in 2021. (RX3296 (Guardant Health, Solutions) at 7; Chudova (Guardant) Tr. 1155, [redacted]

Response to Finding No. 487

Complaint Counsel does not disagree with the proposed finding.

487.1 The ECLIPSE trial's population consists of patients undergoing regular screening procedures for colorectal cancer using colonoscopy, and the aim of the study is to be able to assess performance of Guardant's CRC screening device in comparison to standard of care, which is colonoscopy. (Chudova (Guardant) Tr. 1189; PX7100 (Chudova (Guardant) Dep. at 32–33); (RX3869 (Cote Expert Report) ¶ 210.)

Response to Finding No. 487.1

Complaint Counsel does not disagree with the proposed finding.

488. Guardant has completed a 40–participant, prospective observational pilot study in lung cancer, and is conducting a 590–participant, prospective observational study in the U.S. and a 700 participant, prospective observational study in South Korea to evaluate the LUNAR-2 test in lung cancer. (RX3125 (Guardant) at 1–2); RX3122 (Guardant); RX3124 (Guardant); (RX3869 (Cote Expert Report) ¶ 211.)

Response to Finding No. 488

Complaint Counsel does not disagree with the specific statements made in the proposed finding; the proposed finding is incomplete, however, in that Guardant has completed many studies beyond those specifically listed in the proposed finding. (Complaint Counsel notes that Respondents themselves do not represent that the studies listed are the only studies that Guardant has completed.) Complaint Counsel also notes for completeness that RX3125, RX3122, and RX3124 were not produced by Guardant (as Respondents' citations suggest) but rather appear to have been printed from the internet by Respondents themselves.

489. [redacted]

Response to Finding No. 489

[redacted]

490. [redacted]

Response to Finding No. 490

[redacted]

[redacted]

c. Guardant's Other Oncology Test Development Efforts

491. Guardant currently markets the following types of oncology tests: Guardant360® CDx, a 61–gene panel, FDA-approved therapy selection test; Guardant360® LDT, an 80–gene panel therapy selection test; GuardantOMNI, a 500–gene panel therapy selection test; and Guardant Reveal, an MRD monitoring test. (RX3219 (Guardant)*;* RX3295 (Guardant); (RX3869 (Cote Expert Report) ¶ 214.)

Response to Finding No. 491

Complaint Counsel does not disagree that Guardant currently markets the oncology tests identified in the proposed finding. Complaint Counsel objects to any further characterizations of those tests, such as the numbers of genes on various panels. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. Respondents' citations to RX3219 (a 94-page document) and RX3295 (a 6-page document) do not identify specific page numbers. The citations thus violate the Court's Order and the Court should disregard the proposed evidence. [redacted]

492. Guardant's Guardant360® CDx, Guardant360® LDT and GuardantOMNI tests are therapy selection tests based on NGS sequencing of genomic materials, and would not be sensitive enough for multi-cancer screening tests. (RX3869 (Cote Expert Report) ¶ 215.)

Response to Finding No. 492

The proposed finding, which consists of language copied and pasted from Dr. Cote's report, relies on improper expert opinion. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of

evidence supporting the facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

Furthermore, Dr. Cote is not qualified to provide expert opinion testimony about the process for developing a multicancer screening test because he has no experience developing such tests. [redacted] This Court should not accord Dr. Cote's opinion any weight. In addition to Dr. Cote being unqualified, his opinion about the potential for particular tests to be used as a basis for adaptation and development into MCED tests is unreliable given that he does not even purport to apply any specific methodology to reach his conclusion, let alone one that is reflected in any peer reviewed publication, supported by any well-known regulatory guidance or scientific standard, or accepted by any relevant scientific community.

5. Helio Health

493. Helio Health (formerly known as Laboratory for Advanced Medicine ("LAM")) is a molecular diagnostics company based in Irvine, California. (RX3310 (Helio) at 1, 5; Chahine (Helio) Tr. 1001.) It also has an office in Beijing, China. (RX3310 (Helio) at 1,5.) LAM was founded in 2014. [redacted]

Response to Finding No. 493

[redacted]

494. [redacted]

Response to Finding No. 494

[redacted]

[redacted]

495. [redacted]

Response to Finding No. 495

[redacted]

[redacted]

[redacted]

496. [redacted]

Response to Finding No. 496

[redacted]

[redacted]

497. [redacted]

Response to Finding No. 497

[redacted]

[redacted]

498. There is no indication based on Helio Health's work to date that Helio Health will be a competitor to GRAIL in the foreseeable future, and depending on the test that Helio Health develops in the future, it is unclear if it will be a competitor to GRAIL or will develop a complementary test. (RX3869 (Cote Expert Report) ¶ 217; [redacted]

Response to Finding No. 498

[redacted]

[redacted]

499. [redacted] Helio discloses that its pipeline of cancer testing and screening products, includes tests for colon, breast, lung and "multi-cancer" indications. (RX3308 (Helio) at 1.) Both Helio's recent announcements, as well as its prior work on IvyGene, shows that it has only ever studied four cancers: breast, colon, liver, nasopharyngeal and lung. (RX3302 (Hao et al., 2017); RX3308 (Helio) at 2); RX3616 (Roy et al., 2019).)

Response to Finding No. 499

[redacted]

[redacted]

[redacted]

500. [redacted]

Response to Finding No. 500

[redacted]

[redacted]

501. [redacted]

Response to Finding No. 501

[redacted]

[redacted]

[redacted]

[redacted]

501.1 Helio was previously developing a multi-cancer screening test called IvyGene but has since abandoned those efforts. (PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.)

Response to Finding No. 501.1

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, mischaracterizes the evidence, and is unsupported. The proposed finding is vague because the phrase "abandoned those efforts" is ambiguous and undefined.

There is no page 218 of the Chahine Deposition. Respondents' citation to PX7077 at 218 fails to support the proposed finding. The suggestion that a nonexistent page of a deposition transcript supports a factual finding is itself misleading.

RX3417 describes IvyGene as a test but does not indicate any "abandonment" of "efforts" by Helio. RX3263 appears to be an article from a website called "genomeweb.com" titled "Helio Health Aims to Market Blood-Based Liver Cancer Screening Assay in Early 2021." The "genomeweb.com" article merely states that Helio "has discontinued" its IvyGene assay in

favor of commercializing it Helio Liver Test. (RX3263 (GenomeWeb) at 1). It says nothing about Helio "abandoning" its "efforts" related to IvyGene.

The only other source for the proposed finding is the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence.

502. Dr. Scott Morton has not presented any evidence showing that the Helio two cancer-type test (or even a test screening for five cancer types), including many cancers with an existing cancer screening test, is a close substitute of the Galleri test, which simultaneously screens for more than 50 cancer types, 45 of which have no current screening test. (RX3869 (Cote Expert Report) ¶ 219; [redacted]

Response to Finding No. 502

[redacted]

[redacted]

[redacted]

503. In 2020, Helio Health renamed the IvyGene liver cancer panel to the "Helio Liver Test," and aims to market it in early 2021 as an LDT, followed by an FDA-approved test in 2022. (RX3263 (GenomeWeb) at 1.)

Response to Finding No. 503

Complaint Counsel has no specific response to the proposed finding.

504. In addition to NGS-based cfDNA methylation biomarkers, Helio is also using ELISA to identify protein biomarkers linked to liver cancer, including the alpha-fetoprotein (AFP). (RX3263 (GenomeWeb) at 1.)

Response to Finding No. 504

The proposed finding is vague, misleading, and unreliable. The proposed finding is vague because the term "ELISA" is not defined.

[redacted] Dr. Cote appears to have based his statement on RX3263, which appears to be an article printed from a website called "genomeweb.com." Helio did not produce RX3263. Respondents' reliance on a purported factual statement by their expert based solely on his internet research is inherently unreliable.

[redacted] However, this Court should disregard this proposed finding as specifically phrased for the reasons stated above.

505. Helio is taking a multiomics approach, by combining methylation data, protein biomarkers and patients' demographic information using an AI algorithm to determine whether the patient has early-stage liver cancer. (RX3869 (Cote Expert Report) ¶ 220.)

Response to Finding No. 505

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, relies on improper expert opinion. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support purely factual propositions in contravention of this Court's Order. The Court should disregard this evidence.

505.1 Helio is pursuing a path of using very limited numbers of biomarkers, (9, 8, 5 and even one), and has done some of their clinical studies not with NGS but with ddPCR. (*See* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).).

Response to Finding No. 505.1

The proposed finding, which consists of language copied and pasted from Dr. Cote's report, is vague, misleading, violates the Court's Post-Trial Order, and is against the weight of evidence. The proposed finding is vague because it does not define the terms "pursuing a path," "some," and "very limited."

[redacted] Respondents' attempts to impute Dr. Cote's views (*e.g.*, "very limited") to the authors of the studies cited is improper and unsupported.

Respondents' citations to RX3747 and RX3436 violate this Court's Post-Trial Order. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. Respondents' citations to RX3747 (an 8-page

document) and RX3295 (a 12-page document) fail to identify specific page numbers. The citations thus violate the Court's Order and the Court should disregard the proposed evidence. Additionally, RX3747 and RX3436 appear to be academic articles and were not produced by Helio. Respondents' (Dr. Cote's) citation to these articles does not provide reliable evidence of what Helio, as a corporate entity "is pursuing."

[redacted]

[redacted] For all the above reasons, the Court should disregard the proposed finding.

506. Helio (and LAM) have conducted a few different trials relating to its liver cancer test, including certain trials relying on Bio-Rad's droplet digital platform (ddPCR) rather than NGS. (RX3265 (GenomeWeb) at 1.)

Response to Finding No. 506

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is vague, misleading, and against the weight of evidence. The proposed finding is vague because the phrase "a few different trials" is imprecise and ambiguous, as is the phrase "certain trials."

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 221), even though Respondents do not attribute it to Dr. Cote, and represents his opinion and characterization. Dr. Cote appears to have based his statement on RX3265, which appears to be an article printed from a website called "genomeweb.com." That article was from 2017 and thus obviously does not represent the current state or status of Helio/LAM's research and development efforts.

[redacted]

[redacted]

506.1 In March 2019, LAM presented results of a blinded validation study to evaluate individual panels of DNA methylation markers developed for the detection of liver cancer. (RX3617 (Roy et al., 2019).) In the 154 participant liver cancer panel study with 60 Stage I–IV liver cancer patients, 30 patients of another cancer type, 10 patients with benign liver disease and 30 healthy individuals, the IvyGene liver cancer panel showed an overall sensitivity of 95% and specificity of 97.5%. (RX3617 (Roy et al., 2019); (RX3869 (Cote Expert Report) ¶ 221.)

Response to Finding No. 506.1

The proposed finding is misleading and based on unreliable hearsay. The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report, even though Respondents do not attribute it to Dr. Cote by quotation. (RX3869 (Cote Report) ¶ 221). The only other source cited for the proposed finding is a document of unknown provenance and authenticity that Respondents appear to have printed from the internet. Though no URL address or other information on the source of the proposed finding appears on the document itself, Respondents claim on JX2 that the document was derived from some website called abstractsonline.com. The document was not produced by LAM. Complaint Counsel has no idea who or what abstractsonline.com is. The document certainly is not a full study and was not produced by "Roy et al." An abstract of unknown provenance that was not produced by LAM itself is not a reliable source of what "LAM presented." The underlying source is unreliable hearsay and the Court should disregard the proposed finding.

506.2 In November 2020, Helio presented results of a prospective validation study to evaluate the Helio Liver Test, together with protein markers and demographics, for the detection of liver, breast or colorectal cancers. (RX3618 (Roy et al., 2020).) In the 631–participant study with 291 liver cancer patients and 340 age-matched healthy controls, the multiomics test achieved an overall sensitivity of 93.0% and a specificity of 95.6%, with sensitivities for Stages I, II, III and IV at 77.8%, 99.8%, 96.8%, and 98.6%, respectively, at a 95% specificity. (RX3618 (Roy et al., 2020).)

Response to Finding No. 506.2

The proposed finding, which is pasted verbatim from Dr. Cote's report, is vague and misleading. The proposed finding is vague because the phrase "together with protein markers and demographics" is undefined; it is unclear what the term "demographics" means in the context in which it is used.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 221), even though Respondents do not attribute it to Dr. Cote, and represents his characterizations rather than the language used in the underlying source. For example, RX3618 refers specifically to "hepatocellular carcinoma (HCC)," not "liver cancer." Heptacellular carcinoma is one form of liver cancer; but it is not coterminous with all "liver cancer." The proposed finding's use of Dr. Cote's terminology thus fails to convey precisely the information contained in the underlying document. Complaint Counsel objects to Respondents' unattributed use of expert characterization to attempt to establish fact testimony. Therefore, this Court should disregard the proposed finding.

506.3 Helio further disclosed that the Helio Liver Test alone only achieved sensitivity of 88.7% in Stage I–II liver cancer patients, while sensitivity for AFP alone was 57.5% and for ultrasound was approximately 47%. (RX3308 (Helio) at 1; RX3869 (Cote Expert Report) ¶ 222).

Response to Finding No. 506.3

The proposed finding, which consists of language copied and pasted verbatim from Dr.

Cote's report, is misleading and relies on improper expert opinion.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 222), even though Respondents do not attribute it specifically to Dr. Cote by quotation, and represents his opinion and characterization. Respondents' attempts to impute Dr. Cote's opinions (*e.g.*, "*only* achieve") to Helio is improper and unsupported.

Complaint Counsel does not disagree that the specific statistics listed in the proposed finding correspond to the numbers presented in the press release cited (RX3308). Dr. Cote's statement that the Helio Liver Test alone "only" achieved sensitivity of 88.7% for the detection of Stage I-II liver cancer, however, is itself misleading. As RX3869 notes, ultrasound is "the current standard of care for early-stage HCC detection" and achieves sensitivity of 47% for Stage I-II cancer. That means the Helio Liver Test missed Stage I-II cancers 11.3% of the time, compared to 53% of time for the current "standard of care" for early-stage HCC detection. The Helio Liver Test thus represents a remarkable increase in early-stage liver cancer detection relative to the current standard of care. Dr. Cote's use of the term "only" to attempt to minimize this accomplishment is unsupported and disingenuous.

> 506.4 In February 2019, LAM started a 1,600–participant, prospective observational CLiMB trial to compare the performance of the IvyGene Dx Liver Cancer Test with ultrasound, CT or MRI for the detection of liver cancer within a population that is at high risk for liver cancer due to liver cirrhosis. (RX3127 (Clinicaltrials.gov) at 2.) The CLiMB trial is expected to complete in 2023. (RX3127 (Clinicaltrials.gov) at 2.) The Helio-led team has enrolled at least 500 of 800 high-risk patients and anticipates releasing the results of the trial by early next year. (RX3263 (GenomeWeb) at 3.)

Response to Finding No. 506.4

The proposed finding, which is copied and pasted verbatim from Dr. Cote's report, is misleading, incorrect, and misstates the contents of both RX3127 and RX3263.

The proposed finding is misleading because—like numerous of Respondents' other

proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 223), even though Respondents do not attribute it to Dr. Cote, and imputes Dr. Cote's misreading of RX3127 to the write-up of the study itself.

RX3127 states that the CLiMB trial is "designed to evaluate the performance of the IvyGene Dx Liver Cancer Test alone, ultrasound alone and the combination of both the IvyGene Dx Liver Cancer Test and ultrasound for the detection of HCC within a population that is at high risk for HCC due to liver cirrhosis." (RX3127 at 1 (ClinicalTrials.gov, Clinical Trial for the IvyGene Liver Cancer Test (CLiMB)). The document does not say anything about comparing the performance of IvyGene to "CT or MRI." Dr. Cote appears to have misunderstood or misinterpreted the ClinicalTrials.gov write-up, which explains that "[d]iagnostic imaging by CT or MRI" is one of the methods by which subjects were identified for inclusion in the study – not comparators for the performance of IvyGene. (*See* RX3127 at 4-5 (ClinicalTrials.gov, Clinical Trial for the IvyGene Liver Cancer Test (CLiMB)).

The final sentence of the proposed finding is also unsupported. The cite proffered (RX3263 at 3) fails to support any of the statements made in that sentence.

Complaint Counsel does not disagree that Helio/LAM initiated the CLiMB study in 2019, that the estimated enrollment of the study was 1,6000 participants, that the study is a prospective observational trial, that the trial is designed to compare the performance of the IvyGene Dx Liver Cancer test with *ultrasound*, or that the trial is expected to complete in 2023. The Court should disregard the remainder of the proposed finding as incorrect and/or unsupported.

> 506.5 Helio also partnered with Chinese collaborators to validate the Helio Liver Test in a blinded case-control study, called "Evaluate Methylation Markers for Detection of Liver Cancer Study" (VICTORY). (RX3308 (Helio) at 1.)

Response to Finding No. 506.5

The proposed finding, which consists of language copied and pasted verbatim from Dr.

Cote's report, is vague and unsupported.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 224), even though Respondents do not attribute it to Dr. Cote. Dr. Cote himself provides no citation for his assertion in his own report.

Respondents attempt to fill in that blank by improperly misattributing Dr. Cote's statement to a Helio press release (RX3308), even though the press release fails to support the statements made by Dr. Cote. RX3308 does not mention anything about "Chinese collaborators," and the title "Evaluate Methylation Markers for Detection of Liver Cancer Study" appears nowhere in the source material.

Even if Respondents had cited Dr. Cote's report (which they do not), he could not serve as support for a factual statement under the Court's Post-Trial Order. The Court should disregard the proposed finding.

> 506.6 The study evaluated 1,093 individuals in China with liver cancer and benign liver diseases as well as healthy controls, and Helio "plan[s] to share the encouraging details of the VICTORY trial at a later date." (RX3308 (Helio) at 1.)

Response to Finding No. 506.6

Complaint Counsel has no specific response to the proposed finding.

> 506.7 The results of the VICTORY study, which has not been published yet, was used as the basis of Helio's registration submission for the Helio Liver Test in China. (RX3308 (Helio) at 1; (RX3869 (Cote Expert Report) ¶ 224).

Response to Finding No. 506.7

Complaint Counsel has no specific response to the proposed finding.

6. Natera

507. Natera, Inc. ("Natera") is a molecular diagnostics company based in San Carlos, California and Austin, Texas. (*See* PX0155 (Natera).) Natera was founded in 2004 with an

initial focus on genetic testing in women's health, including non-invasive prenatal testing ("NIPT"). (RX3488 (Natera) at 5.)

Response to Finding No. 507

[redacted]

508. [redacted]; RX3492 (May 2019 Earnings Call) at 6; [redacted]

Response to Finding No. 508

[redacted]

[redacted]

[redacted]

509. [redacted]

Response to Finding No. 509

[redacted]

[redacted]

510. While data from a different context may be helpful preliminarily for biomarker discovery purposes, it is unlikely to accelerate the development of a cancer screening test for multiple cancer types or to add a new cancer type to an existing screening test. [redacted]

Response to Finding No. 510

[redacted]

[redacted]

510.1 [redacted]

Response to Finding No. 510.1

[redacted]

[redacted]

[redacted]

511. There is no evidence based on Natera's work to date that Natera will be a competitor to GRAIL in the foreseeable future, and depending on the test that Natera develops in the future, it is unclear if it will be a competitor to GRAIL or will develop a complementary test. (RX3869 (Cote Expert Report) ¶ 227; [redacted]

Response to Finding No. 511

[redacted]

Respondents cite to paragraph 227 of Dr. Cote's report, but Dr. Cote himself provides no citation or support for his statement. [redacted]

Dr. Cote is also not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

In addition to Dr. Cote being unqualified, his opinion is unreliable given that he does not even purport to be performing any analysis subject to or reflected in any peer reviewed publication, supported by any well-known regulatory guidance or scientific standard, or accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

[redacted]

512. To date, Natera has not published any studies relating to cancer screening. (RX3869 (Cote Expert Report) ¶ 228.) [redacted]

Response to Finding No. 512

[redacted]

[redacted]

513. [redacted]

Response to Finding No. 513

[redacted]

514.

Response to Finding No. 514

[redacted]

515. [redacted]

Response to Finding No. 515

[redacted]

516. [redacted]

Response to Finding No. 516

[redacted]

[redacted]

[redacted]

516.1 [redacted]

Response to Finding No. 516.1

[redacted]

[redacted]

[redacted]

516.2 Further, Natera contends that it will be able to use the biomarkers that it has identified for its Signatera MRD test. (RX3869 (Cote Expert Report) ¶ 230.) However, Natera's CEO as recently as November 2020 stated to its investors that "Signatera technology is not something that can be used for early detection." (RX3496 (Nov. 5, 2020 Earnings Call) at 18.) [redacted]

Response to Finding No. 516.2

[redacted]

[redacted]

517. The MRD test that Natera has developed actually depends on the pre-diagnosis of cancer. (RX3869 (Cote Expert Report) ¶ 230.) The Natera MRD test is based on identifying

DNA point mutations that are specific to an individual patient's cancer, and each patient requires assessment of their cancer cells to identify the mutations that cancer might have. (*See* RX3601 (Reinert et al., 2019); RX3157 (Coombes et al., 2019); RX3118 (Christensen et al., 2019).) This type of assay is inapplicable to a cancer screening test, which is performed in asymptomatic individuals who do not have a cancer diagnosis or tumor tissue to analyze. (RX3869 (Cote Expert Report) ¶ 231.)

Response to Finding No. 517

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's expert report, relies on improper expert testimony and violates the Court's Post-Trial Order. The first sentence of the proposed finding is a factual statement for which Respondents cite only Dr. Cote's report. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence.

The second sentence – which is also pasted directly from Dr. Cote's expert report – is improper and violates the Court's Post-Trial Order. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." Order on Post-Trial Findings at 3. RX3601, RX3517, and RX3118 are 8-page, 31-page, and 12-page documents, respectively. Respondents provide no page citations to any of these sources. The Court should disregard this evidence.

The final sentence relies on improper expert opinion. Dr. Cote is not qualified to provide expert opinion testimony about the process for developing a multicancer screening test because he has no experience developing such tests. [redacted] In addition, Dr. Cote's opinion is unreliable. Dr. Cote's report states, with no citation whatsoever:

"*As is obvious*, this type of assay is inapplicable to a cancer screening test, which is performed in asymptomatic individuals who do not have a cancer diagnosis or tumor tissue to analyze." (RX3869 (Cote Report) ¶ 231 (emphasis added)). Claiming that something "is obvious" with no explanation, methodology, or citation is inherently unreliable. (Perhaps that is why Respondents chose to omit Dr. Cote's "As is obvious" phrase when pasting his language into the proposed finding.) Certainly, the methodology of "declaring things obvious" has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and has not been be accepted by any relevant scientific community. This proposed finding of fact should be disregarded.

518. Even if there was a way for Natera to adopt the tumor profiling results it has collected for a cancer screening test, there are several issues that would structurally impede any rapid adaptation of its findings to such an test: (RX3869 (Cote Expert Report) ¶ 232.)

Response to Finding No. 518

This proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, relies on improper expert opinion. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote in contravention of this Court's Order.

Furthermore, Dr. Cote is not qualified to provide expert opinion testimony about the process for developing a multicancer screening test because he has no experience developing such tests. [redacted] This Court should not accord Dr. Cote's opinion any weight. In addition to Dr. Cote being unqualified, his opinion about the potential for particular tests to be used as a basis for adaptation and development into MCED tests is unreliable given that he does not even purport to apply any specific methodology to reach his conclusion, let

alone one that is reflected in any peer reviewed publication, supported by any well-known regulatory guidance or scientific standard, or accepted by any relevant scientific community.

This Court should disregard this evidence.

518.1 [redacted]

Response to Finding No. 518.1

[redacted]

[redacted]

[redacted]

518.2 [redacted]

Response to Finding No. 518.2

[redacted]

[redacted]

519. [redacted] Thus, any early cancer screening test Natera may develop is likely to be further delayed after the development of the non-tumor-informed MRD panel is complete. (RX3869 (Cote Expert Report) ¶ 233.)

Response to Finding No. 519

[redacted]

[redacted]

[redacted]

[redacted]

520. [redacted]

Response to Finding No. 520

[redacted]

[redacted]

521. [redacted]

Response to Finding No. 521

[redacted]

[redacted]

[redacted]

522. [redacted]

Response to Finding No. 522

[redacted]

[redacted]

523. [redacted]

Response to Finding No. 523

[redacted]

524. [redacted]

Response to Finding No. 524

[redacted]

[redacted]

525. [redacted]

Response to Finding No. 525

[redacted]

[redacted]

526. [redacted] The significance of this prior work is undermined by Natera's own subsequent

strategic decisions regarding the development of its putative cancer screening tests. (PFF ¶¶ 526.1–526.3.)

Response to Finding No. 526

[redacted]

526.1 [redacted]

Response to Finding No. 526.1

[redacted]

[redacted]

526.2 Natera's own public statements show that while Natera may have been focused on early detection around the time of its IPO, it clearly shifted its focus to MRD and has only recently turned its focus back to early detection: until its recent shift, Natera appears to have last mentioned its efforts in early detection in 2016 and 2017. (RX3495 (Natera) at 7 (discussing exploring breast and ovarian cancer screening); RX3491 (Natera) at 18.

Response to Finding No. 526.2

The proposed finding is vague, confusing, misleading, and improper. The proposed finding is vague because the phrases "focused on," "around the time," "shifted its focus," "recently," "turned its focus back," and "recent shift" and "its efforts in early detection" are all ambiguous and undefined. The proposed finding is also vague and confusing because it is unclear what Respondents mean by the phrase "Natera appears." A proposed statement of "appearance" is something other than a proposed statement of "fact" and as such the Court should disregard it.

The proposed finding is improper because it is an argument rather than a factual statement. Respondents merely cite two pages from Natera earnings calls in 2016 and 2017 (RX3495 and RX3491). The documents do not support any part of the proposed finding. They obviously cannot support Respondents' claims about supposed recent shifts in Natera's "focus" (subsequent to 2016/2017). They also cannot, by themselves, establish that Natera did not mention "its efforts in early detection" subsequently. The proposed finding is thus unsupported.

[redacted] The Court should disregard the proposed finding.

526.3 By early 2019, CEO Steve Chapman said, "I want to level set on the market opportunity and where we are positioned. ***We're not focused on asymptomatic cancers strain or early detection.***" (RX3492 (Natera) at 6.)

Response to Finding No. 526.3

[redacted]

7. **Singlera**

527. Singlera Genomics ("Singlera") is a molecular diagnostics company based in La Jolla, California. (PX2780 (Singlera) at 1.) Singlera was founded in 2014 to focus on early cancer detection. (PX7102 (Gao (Singlera) Dep. at 16, 17; 97–98).)

Response to Finding No. 527

Complaint Counsel has no specific response to this proposed finding.

528. Though Singlera has been focusing on early cancer screening for seven years, it still views itself as "early in the run." (PX7102 (Gao (Singlera) Dep. at 17).)

Response to Finding No. 528

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 237), even though Respondents do not attribute it to Dr. Cote, and represents his opinion rather than market realities.

The proposed finding is vague, as it is unclear what "still early in the run" means because it lacks any context. Moreover, the testimony was given in response to a question it appears the witness may not have fully understood. "Q. Now, in your investigational hearing, did you testify that Singlera is a – an early cancer detection company? A. Yes. And depends how we define early. It started in 2014, seven years past, but we still consider ourselves still early in the run." (PX7102 (Gao (Singlera) Dep. at 17).

The proposed finding is misleading and against the weight of the evidence to the extent Respondents imply Singlera is not actively developing its PanSeer MCED test. Singlera has already completed a proof-of-concept study of its PanSeer test in China on 100,000 people, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the development of the PanSeer MCED test and expects to launch it as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)).

[redacted] For the above reasons, the Court should disregard the proposed finding.

529. It appears that Singlera is in the research and development stage for a cancer screening test for five cancer types, and in the clinical stage for its ColonES colorectal cancer screening test. (RX3869 (Cote Expert Report) at ¶ 237.)

Response to Finding No. 529

The proposed finding is misleading because Respondents omit an important qualification from Dr. Cote's report: [redacted] Dr. Cote's musings on "the evidence" based on the limited evidence he personally reviewed are irrelevant and represent unreliable and improper expert opinion.

The proposed finding is vague as to what is meant by "research and development stage" and "clinical stage."

The proposed finding is misleading to the extent it suggests that MCED test developers

all must follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline that Dr. Cote invented in his flawed analysis. [redacted]

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Dr. Cote is also not a credible witness. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)). In addition to being unqualified and not credible, Dr. Cote's opinions

about the process and timeline for developing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

This proposed finding improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source of underlying facts of which he has no personal knowledge, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

530. [redacted]

Response to Finding No. 530

[redacted]

[redacted]

[redacted]

a. Singlera's PanSeer Test

531. Singlera's PanSeer test is a pipeline NGS-based cfDNA methylation RUO cancer screening test that uses Singlera's cell-free methylated DNA immunoprecipitation sequencing ("cfMeDIP-seq") method that is capable of methylome analysis of small quantities (1–10 ng) of cfDNA to provide broad insight into genome-wide DNA methylation patterns of cfDNA without the increased costs associated with whole-genome sequencing. (*See* RX3628 (Shen et al., 2019).)

Response to Finding No. 531

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 239), even though Respondents do not attribute it to Dr. Cote, and represents his opinion rather than market realities.

The proposed finding is vague because the terms "pipeline," "RUO," "immunoprecipitation," and "increased costs" are undefined.

The proposed finding is unsupported because the evidence cited does not mention Singlera or PanSeer.

The proposed finding is misleading to the extent its characterization of Singlera's PanSEER test as "pipeline" and "RUO" suggests that Singlera is not making substantial progress commercializing its test. The proposed finding is against the weight of the evidence showing that [redacted]

This proposed finding improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source of underlying facts of which he has no personal knowledge, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

532. PanSeer examines about 10,613 to over 20,000 methylation markers in cfDNA for the detection of five (5) cancer types – colorectal, esophageal, liver, lung, and stomach. (RX3115 (Chen et al., 2020) at 3; RX3637 (Singlera) at 1–8; Gao (Singlera) Tr. 2874–75.)

Response to Finding No. 532

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 239), even though Respondents do not attribute it to Dr. Cote, and represents his opinion rather than market realities.

Complaint Counsel objects to the attribution of RX3637 (which Respondents appear to have captured from Singlera's website) to Singlera as the source of the document (Singlera did not produce the document), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document constitutes hearsay, and given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is vague in its use of "10,613 to over 20,000 methylation markers" as it does not explain the basis or context for this claim or describe these methylation markers in any way.

This Court should disregard this evidence.

533. The PanSeer test only requires approximately 2 million sequencing reads per sample, and is compatible with both Illumina's MiSeq or NextSeq systems and Thermo Fisher's Ion Torrent S5 systems, though it appears to primarily use the NextSeq 550Dx system from Illumina. (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239.)

Response to Finding No. 533

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents his opinion rather than market realities.

The proposed finding is vague because it does not define "compatible." The proposed

finding is misleading because it says the PanSeer test is compatible with Thermo Fisher's Ion Torrent S5 system but appears to "primarily" use the Illumina NextSeq 550Dx. In fact, although the PanSeer test may in theory be "compatible" with the Thermo Fisher Ion Torrent S5 instrument, that does not mean that the Thermo instrument has the cost, accuracy, and throughput necessary to support developing and commercializing Singlera's PanSeer MCED test; moreover, none of the evidence cited in the proposed finding establishes that the PanSeer test has ever actually been run the Thermo Fisher Ion Torrent S5 system even a single time.

The proposed finding is misleading because it claims that the PanSeer test only requires approximately 2 million sequencing reads per sample. The source Respondents cite for this claim—RX3115—is a paper that was submitted in March 2020 concerning a research study conducted prior to that date. Importantly, RX3115 describes only the version of Singlera's PanSeer test that was used in that now several-year-old study. More recent evidence shows that the PanSeer test requires a higher number of reads per patient sample. As Dr. Gao testified, the PanSeer test as of the date of his deposition (June 2, 2021) requires "a few million to 10 million [reads] for each individual," yielding between "50 to a hundred" patient samples). (PX7102 (Gao (Singlera) Dep. at 78-79). Indeed one hundred patient samples times ten million reads per sample yields 400 million reads, which is the specification for the number of reads that can be generated in one run of the Illumina NextSeq Dx that PanSeer uses for its test. (PX0114 (Illumina) at 2 (Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)). Moreover, Dr. Gao testified that those numbers apply to the colorectal cancer version of the PanSeer test. (PX7102 (Gao (Singlera) Dep. at 78). Importantly, Dr. Gao testified that the pan-cancer version of the PanSeer test "could be less" patient samples per run—"between 20 to 50." (PX7102 (Gao (Singlera) Dep. at 78-79).

Accordingly, any suggestion that the current pan-cancer version of Singlera's PanSeer test in development requires only 2 million reads per patient sample is misleading and against the weight of recent evidence demonstrating that the number is much higher. The Court should disregard the proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED testing, because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not a credible witness. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)). In addition to being unqualified and not credible, Dr. Cote's opinions about which NGS platforms are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

534. In a retrospective, observational study of 418 participants from part of the Taizhou Longitudinal Study with samples from 113 post-diagnosis cancer patients, 98 pre-diagnostic cancer patients, and 207 healthy individuals, PanSeer achieved a 96.1% specificity, 87.6% sensitivity in post-diagnostic cancer patients, and 94.9% sensitivity in 98 pre-diagnostic cancer patients. (RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.) Singlera envisions, however, that any patient testing positive on PanSeer would then undergo additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3869 (Cote Expert Report) ¶ 239; RX3115 (Chen et al., 2020) at 6.)

Response to Finding No. 534

The proposed finding, which consists of language copied and pasted from Dr. Cote's expert report, is misleading, confusing, and mischaracterizes cited evidence.

The first sentence of the proposed finding is not supported by the citations listed by

Respondents. Neither RX3637 nor the trial testimony of Dr. Gao provides or lists the specific numbers Respondents reference in the proposed finding. It is unclear from where Respondents are drawing these numbers. To the extent Respondents attribute them to the cited sources, Respondents mischaracterize those sources. As written and cited, the first sentence is unsupported and unreliable. The court should disregard the proposed finding.

The second sentence of the proposed finding purports to provide a factual account about what "Singlera envisions." The primary source cited for the proposed finding is the expert report of Dr. Cote. This Court ordered, however, that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support factual propositions in contravention of this Court's Order. The Court should disregard this evidence.

The only other cite for the second sentence of the proposed finding is a citation to RX3115 (Chen et al., Non-invasive Early Detection of Cancer Four Years Before Conventional Diagnosis Using a Blood Test, Nature, 2020)). RX3115 is an academic paper. The authors do not purport to be speaking for Singlera as a corporate entity. It is not sensible to cite the article as evidence of what "Singlera," as a corporate entity, envisions. (The lead author, for example, lists several affiliations with various innovation centers and institutes of health, but does not list any specific business affiliation with Singlera itself.)

The proposed finding is confusing because its (Dr. Cote's) use of the term "however" does not make grammatical sense. Even if the two sentences in the finding were properly supported (which they are not), nothing in the proposed language of the second sentence would in any way contradict or counter any of the proposed language in the first sentence of the first finding.

Finally, the proposed finding is misleading to the extent it suggests that patients who test positive on Galleri would not need to "undergo additional blood test and/or follow-up imaging." Aa positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," notwithstanding Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.)

Interim results from PATHFINDER, an actual interventional trial for Galleri, indicate that additional imaging testing was required for positive results 90 percent of the time. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) ("Most participants with diagnostic resolution had at least 1 imaging test (57/63; 90%).").

The Court should disregard the proposed finding.

534.1 [redacted] In fact, only a very small portion of the samples from 100,000 participants of the Taizhou Longitudinal Study were used. (RX3115 (Chen et al., 2020) at 3; RX3869 (Cote Expert Report) n. 38.)

Response to Finding No. 534.1

[redacted]

[redacted]

535. [redacted] No analytical or clinical data that Singlera has collected provides support for the proposition that PanSeer can detect more than 5 cancer types, let alone 50 or 150 cancer types. (Gao (Singlera) Tr. 2917–18; RX3869 (Cote Expert Report) ¶ 241; [redacted]

Response to Finding No. 535

[redacted]

[redacted]

536. [redacted]
However, Singlera's subsequent deposition testimony suggests that such a timeline does not appear to be feasible. (Gao (Singlera) Tr. 2925–27, 2942–43, 2949; PX7102 (Gao (Singlera) Dep. at 81–85).)

Response to Finding No. 536

[redacted]

[redacted]

536.1 In particular, Singlera testified that it is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82.) For a pan-cancer trial, Singlera estimates that a clinical trial would need to be for 100,000 or 200,000 people, somewhere around eight or 10 years. (Gao (Singlera) Tr. 2925–26; PX7102 (Gao (Singlera) Dep. at 122–23).).

Response to Finding No. 536.1

[redacted]

The proposed finding is misleading [redacted]

[redacted] The proposed finding is against the weight of the evidence showing that [redacted]

[redacted]

536.2 Therefore, by Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States. (Gao (Singlera) Tr. 2925–26; RX3869 (Cote Expert Report) ¶ 242.)

Response to Finding No. 536.2

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and represents his opinion rather than market realities.

The proposed finding is misleading to the extent its characterization of Singlera's PanSEER test as "pipeline" and "RUO" suggests that Singlera is not making substantial progress commercializing its test. The proposed finding is against the weight of the evidence showing that [redacted]

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Dr. Cote is also not a credible witness. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems

across these subjects)). In addition to being unqualified and not credible, Dr. Cote's opinions about the process and timeline for developing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

This proposed finding improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source of underlying facts of which he has no personal knowledge, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

> 536.3 Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 242.); Gao (Singlera) Tr. 2926; Cote Tr. 3869.)

Response to Finding No. 536.3

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and represents his opinion rather than market realities.

The proposed finding is misleading to the extent its characterization of Singlera's PanSEER test as "pipeline" and "RUO" suggests that Singlera is not making substantial progress commercializing its test. The proposed finding is against the weight of the evidence showing that [redacted]

[redacted]

Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Dr. Cote is also not a credible witness. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)). In addition to being unqualified and not credible, Dr. Cote's opinions about the process and timeline for developing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

This proposed finding improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source of underlying facts of which he has no personal knowledge, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

b. Singlera's ColonES® Tests

537. In addition to the PanSeer cancer screening test in development, Singlera is also developing single cancer screening tests for colorectal cancer and likely lung cancer. (Gao (Singlera) Tr. 2872–73; RX3869 (Cote Expert Report) ¶ 243.)

Response to Finding No. 537

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and

represents his opinion rather than market realities.

The proposed finding is unsupported because the testimony cited does not mention a screening test for lung cancer.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for a purported underlying fact—that Singlera is developing a single cancer test for "likely lung cancer"—in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

538. The ColonES® rapid colon cancer assay is a targeted bisulfite NGS sequencing test of ctDNA methylation signatures from blood plasma. (Gao (Singlera) Tr. 2873–74; RX3869 (Cote Expert Report) ¶ 244.)

Response to Finding No. 538

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and represents his opinion rather than market realities.

The proposed finding is unsupported because the testimony cited does not state or support that ColonES uses "targeted bisulfite NGS sequencing" or "blood plasma" samples. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source of underlying facts for which he has no personal knowledge, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

539. Singlera reported that it had an initial Pre-Submission Meeting with the FDA regarding its ColonES® test in the fall of 2019, and a second Pre-Submission Meeting on April

21, 2020, and that Singlera planned to start the ColonES® pivotal study in the United States in the second half of 2020. (RX3635 (Singlera) at 1–2.)

Response to Finding No. 539

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 244), even though Respondents do not attribute it to Dr. Cote, and represents his opinion rather than market realities.

Complaint Counsel objects to the attribution of RX3635 to Singlera. RX3635 appears to be a document about a Singlera press release that Respondents captured from an unknown source, as it contains no URL. The document was not produced by Singlera. This document constitutes unreliable hearsay, and given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)). This Court should disregard this evidence and the proposed finding.

540. In 2018, Singlera reported the results of its ColonES retrospective study to screen for early stage colorectal cancer and precancerous advanced adenomas. (RX3869 (Cote Expert Report) ¶ 244.)

Response to Finding No. 540

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and represents his opinion rather than market realities.

The proposed finding improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source for the purported fact about Singlera reporting its study results, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

540.1 In this 1,243 participant study with 291 Stage I colorectal cancer patients, 133 Stage II patients, 124 Stage III patients, and 102 Stage IV patients, 204 advanced adenomas patients and 429 healthy individuals, the ColonES® test achieved sensitivities of 93% for colorectal cancer and 88% for advanced adenoma with a specificity of 99%. (RX3636 (Singlera) at 1–2; RX3273 (Gole et al., 2018); RX3869 (Cote Expert Report) ¶ 244.)

Response to Finding No. 540.1

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and represents his opinion rather than market realities.

The proposed finding improperly cites expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source for purported facts about Singlera's study, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

541. Singlera has also conducted a prospective, observational study in China of 300 participants for the detection of early-stage lung cancer. (RX3130 (Clinicaltrials.gov) at 1–5.) Singlera has not reported results of this study yet. (RX3869 (Cote Expert Report) ¶ 245.)

Response to Finding No. 541

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and represents his opinion rather than market realities.

This proposed finding is improper expert opinion. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as a source for purported facts about Singlera's study, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

542. Despite these efforts with clinical trials in China, Singlera believes that it is "far from" starting FDA clinical trials for ColonES in the United States. (PX7102 (Gao (Singlera) Dep. at 113).) Singlera testified that it will need a three to four year study for at least 10,000 people for the trial. (PX7102 (Gao (Singlera) Dep. at 120–21); Gao (Singlera) Tr. 2923.) In addition, Singlera is considering a qPCR version—not NGS—of the ColonES test to be launched in China first. (PX7042 (Gao (Singlera) IHT at 90–91); Gao (Singlera) Tr. 2911–12.) Therefore, by its own admission, Singlera appears to anywhere from three to seven years away from completing clinical trials for ColonES, and likely even longer. (RX3869 (Cote Expert Report) ¶ 246; Gao (Singlera) Tr. 2923.)

Response to Finding No. 542

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report, and represents his opinion rather than market realities.

The proposed finding is misleading to the extent it suggests Singlera is years away from starting FDA clinical trials for ColonES in the United States, because Dr. Gao testified that by "far" away he means one year. (Gao (Singlera) Tr. 2921) ("Well, I already told you. My 'far' is one year.")).

The proposed finding is vague because it is not clear what "these efforts with clinical trials in China" references. The proposed finding is also vague because it does not define "likely even longer."

The proposed finding is unsupported because the testimony cited to support the misleading and conclusory claim that "Singlera appears to be anywhere from three to seven years away from completing clinical trials for ColonES, and likely even longer" simply provides no support for the point. (Gao (Singlera) Tr. 2923).

The only other evidence cited for this purported point is Dr. Cote's report, which is improper expert testimony. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote in contravention of this Court's Order. This

Court should disregard this evidence.

The proposed finding is misleading to the extent it suggests that qPCR-based detection systems are a viable platform for MCED testing. The proposed finding is against the weight of significant evidence demonstrating that PCR-based detection platforms (such as qPCR and dPCR) cannot be used for MCED testing. (*See* CCFF ¶¶ 1441-93). Therefore, this Court should disregard the proposed finding.

C. Non-NGS Cancer Screening Developers

1. StageZero

543. StageZero Life Sciences ("StageZero"), formerly known as Genenews, is a molecular diagnostics company based in Richmond Hill, Canada and Richmond, Virginia. (PX8542 (StageZero) at 1.)

Response to Finding No. 543

[redacted]

544. [redacted]

Response to Finding No. 544

[redacted]

[redacted]

545. StageZero was founded in 2000, and began working on its colorectal cancer screening test (called ColonSentry) in 2003. (PX7114 (Stamatiou (StageZero) Dep. at 10–11, 25).) [redacted]

Response to Finding No. 545

[redacted]

546. StageZero intends to provide, on a limited basis to a network of oncologists, a microarray-based cancer screening LDT test, together with partners Health Clinics and Care Oncology, called Aristotle. (RX3659 (StageZero) at 1.)

Response to Finding No. 546

[redacted]

[redacted]

547. Aristotle is a microarray-based blood biopsy test that interrogates mRNA from whole blood (blood transcriptome) to detect gene expression profiles indicative of 10 discrete cancers. (RX3171 (Dempsey et al., 2020) at 1–2.)

Response to Finding No. 547

[redacted]

[redacted]

548. Aristotle will detect 9 cancers relevant for women (the "female" test): ovarian, breast, cervical, endometrial, colorectal, bladder, stomach, liver and nasopharyngeal, and 6 cancers for men (the "male" test): prostate, colorectal, bladder, stomach, liver and nasopharyngeal. (RX3653 (StageZero) at 4; [redacted] RX3869 (Cote Expert Report) ¶ 248.)

Response to Finding No. 548

[redacted]

549. In contrast to the DNA methylation or genomic mutation based approaches used by GRAIL, Thrive, and other companies, StageZero uses an approach called immunoediting, under the theory that when normal cells transform into clinically-detectable cancer, the human immune system protects the human body from cancer and forces the developing tumors to undergo immunogenic "sculpting" through three phases: elimination, equilibrium and escape. (RX3643 (Smyth et al., 2006) at 1–50.)

Response to Finding No. 549

The proposed finding relies on unreliable hearsay evidence and is misleading and vague. The sole citation to this proposed finding is to a sixteen-year-old journal article. Respondents are

using out of Court statements contained in this article to describe the science of StageZero's approach. As this is being presented for the truth of the matter contained, it is unreliable hearsay evidence. The overall reliability of this article is questionable, at best. A sixteen-year-old journal article is hardly reliable evidence to describe StageZero's current scientific approach. Furthermore, although Respondents proposed finding mentions StageZero's approach in comparison to Grail, Thrive and unidentified "other companies," the article itself offers no comparison—not surprising as it is sixteen years old. It is impossible therefore to assess how meaningful it is that StageZero uses "immunoediting" without more description of how StageZero compares to these others. For this reason, this proposed finding is vague and confusing. This proposed finding is also vague because the terms "immunoediting" and "immunogenic 'sculpting'" are undefined.

Respondents' citation to RX3643 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3454 is a 50-page document, so Respondents' citation to pages 1-50 comprises the entire document. Thus, Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 249). Therefore, the Court should disregard the proposed finding.

> 549.1 As a result of this immunoediting, gene expressions in the transforming cancer cells, *i.e.*, the mRNA from the transcriptome, display signature profiles, and cause a corresponding change in the mRNA profiles in the peripheral blood plasma. (RX3869 (Cote Expert Report) ¶ 249.)

Response to Finding No. 549.1

The proposed finding is improper, unreliable, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 249; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 249). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

Dr. Cote is not qualified to provide expert opinion testimony about StageZero's process for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Furthermore, Dr. Cote is not a credible witness. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise, and his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)). Because Dr. Cote is unqualified and not credible, his opinion does not deserve any weight.

The proposed finding is vague because the terms "immunoediting," "transcriptome," "signature profiles," and "peripheral blood plasma" are undefined. Therefore, the Court should disregard the proposed finding.

549.2 StageZero's Aristotle detects this change using Thermo Fisher/Affymetrix's GeneChipTM Gene Expression Profile microarray—not NGS—which tests more than 36,000 gene transcripts and variants. (RX3171 (Dempsey et al., 2020) at 1–2.)

Response to Finding No. 549.2

[redacted]

[redacted]

550. In a 2,845 unique blood samples validation study with 1,013 samples from patients diagnosed with 10 cancers and 1,832 control samples including 1,042 samples from healthy subjects and the remaining from patients diagnosed with non-cancer diseases, Aristotle achieves sensitivity from 55.6% to 100% for various cancers at 99.0% specificity, with PPVs from 5.6–77.7% and mean false positive rate ranging from 0.3% to 6.8%. (RX3171 (Dempsey et al., 2020) at 1–2.)

Response to Finding No. 550

The proposed finding is misleading and vague. The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 249). The proposed finding is vague because the term "10 cancers" is ambiguous. It is unclear whether the 10 cancers referenced in the proposed finding align with the cancers that StageZero claims Aristotle can detect. Therefore, the Court should disregard the proposed finding.

551. StageZero states that the Aristotle test can fully discriminate each cancer, but has not fully disclosed how the tissue of the origin of the cancers are determined. (RX3653 (StageZero) at 1–4.) [redacted]

Response to Finding No. 551

[redacted]

[redacted]

552. [redacted] StageZero currently does not have any multi-cancer clinical trial listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 251.)

Response to Finding No. 552

[redacted]

2. **Genesys Biolabs**

553. Genesys Biolabs, a business unit of 20/20 GeneSystems, Inc., is a molecular diagnostics company based in Rockville, Maryland. (RX3869 (Cote Expert Report) ¶ 252.) Genesys Biolabs currently provides a cancer screening test for lung, liver, pancreas, ovaries, kidneys, prostate and colon cancers. (RX3869 (Cote Expert Report) ¶ 252.)

Response to Finding No. 553

The proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be

established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 252; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 252). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the term "business unit" is ambiguous and undefined.

554. Genesys Biolabs currently provides a proteomics-based LDT blood test, called OneTestTM. (RX3259 (Genesys Biolabs) at 1.) OneTest measures a panel of seven widely used cancer protein biomarkers (AFP, CEA, PSA, CA 19–9, CA 125, CA 15–3, and CYFRA 21–1)—not NGS—from a single blood biopsy sample, to simultaneously screens for cancers from the lung, liver, pancreas, ovaries, kidneys, prostate and colon using immunoassay on the Roche Cobas e411 immunoassay analyzer. (RX3259 (Genesys Biolabs) at 1.)

Response to Finding No. 554

The proposed finding is unsupported, unreliable hearsay evidence, misleading, and vague. Complaint Counsel objects to the attribution of RX3259 which Respondents purportedly captured from OneTestForCaner's website to Genesys Biolabs as the source of the document, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3.) The document was not produced by Genesys Biolabs. Respondents elected not to pursue any form of discovery from Genesys Biolabs in this action. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by Genesys Biolabs, which Respondents offer for the truth and

attribute to a party that did not testify in this proceeding. Given the inherent unreliable nature of the document, it lacks probative value (*see* Rule 4.43(b)). This court should disregard RX3259.

The proposed finding is unsupported because RX3259 does not identify OneTest as a proteomics-based LDT test and does specify that OneTest uses immunoassay on the Roche Cobas e411 immunoassay analyzer. (RX3259 at 1 (One Test for Cancer: Why Get Tested, https://onetestforcancer.com/learn)).

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 253).

The proposed finding is vague because the terms "immunoassay" and "Roche Cobas e411 immunoassay analyzer" are undefined. Therefore, the Court should disregard the proposed finding.

555. In a prospective observational study of 41,516 participants taking health check-up examination at the Chang Gung Memorial Hospital in Taoyuan, Taiwan between May 2001 and April 2013, the OneTest panel of protein biomarkers, together with squamous cell-specific antigen, a biomarker associated with head and neck cancer not common in the U.S., achieved 57% sensitivity at 88.7% specificity, with PPV of 3.7%, and NPV of 99.6%. (RX3739 (Wen et al., 2015) at 2.)

Response to Finding No. 555

The proposed finding is misleading, vague, and relies on unreliable hearsay evidence. The proposed finding is misleading to the extent that it suggests the Chang Gung Memorial Hospital study only measured OneTest's ability to detect head and neck cancer. As outlined in the Wen et al. article (RX3739), the Chang Gung Memorial Hospital study measured OneTest's ability to detected 18 different cancers, which the test did with varying degrees of specificity and sensitivity. (RX3739 at 002 (Wen et al., Cancer Screening through a Multi-Analyte Serum Biomarker Panel During Health Check-Up Examinations, *Clinica Chimica Acta* 450 (2015); *see*

also RPFF ¶ 555.1). Thus, the statistics for head and neck cancer should be taken as representative of the entire study. The proposed finding is also misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 253).

This proposed finding also contains unreliable hearsay evidence. This is a journal article being used to represent the capabilities of OneTestPanel, not a document was produced by Genesys Biolabs, the purported owner of OneTestPanel. Respondents elected not to pursue any form of discovery from Genesys Biolabs in this action. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by Genesys Biolabs, which Respondents offer for the truth. This journal article is six years old and therefore is not a reliable source for the current capabilities of the OneTestPanel.

The proposed finding is vague because the term "squamous" is undefined. Therefore, the Court should disregard the proposed finding.

> 555.1 The panel's sensitivity for liver, lung, prostate, and colorectal cancers was 90.9%, 75.0%, 100%, and 76.9%, respectively, but the panel had a poor sensitivity for identifying head and neck cancer (17.6%), breast cancer (37.5%), and cervical cancer (44.4%). (RX3739 (Wen et al., 2015) at 2.)

Response to Finding No. 555.1

The proposed finding is incomplete, contains unreliable hearsay evidence, misleading, and vague. The proposed finding is incomplete because it does not include the fact that liver, lung, prostate, and colorectal cancers are the most four commonly diagnosed cancers. RX3739 repeatedly mentions this fact when listing the high rate of sensitivity for liver, lung, prostate, and colorectal cancers. (RX3739 at 001, 002 (Wen et al., Cancer Screening through a Multi-Analyte Serum Biomarker Panel During Health Check-Up Examinations, *Clinica Chimica Acta* 450 (2015)).

The proposed finding is also misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 253).

This proposed finding also contains unreliable hearsay evidence. This is a journal article being used to represent the capabilities of OneTestPanel, not a document was produced by Genesys Biolabs, the purported owner of OneTestPanel. Respondents elected not to pursue any form of discovery from Genesys Biolabs in this action. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by Genesys Biolabs, which Respondents offer for the truth. This journal article is six years old and therefore is not a reliable source for the current capabilities of the OneTestPanel.

The proposed finding is vague because the term "the panel" is ambiguous. Therefore, the Court should disregard the proposed finding.

556. Genesys Biolabs currently does not have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 254.)

Response to Finding No. 556

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 254; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 254). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and

otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

3. InterVenn Biosciences

557. InterVenn Biosciences ("InterVenn") is a biotechnology company based in South San Francisco, California. (RX3388 (InterVenn) at 1.) InterVenn is known to be developing early cancer detection tests for advanced adenoma, colorectal cancer and nasopharyngeal carcinoma. (Leite (Illumina/InterVenn) Tr. 2171–74.) InterVenn is also developing a population diagnostic test for ovarian cancer; a therapy selection test for pancreatic cancer, lung cancer and melanoma, called Dawn; and a renal cell carcinoma test. (Leite (Illumina/InterVenn) Tr. 2170, 2172, 2180; *see also* RX3869 (Cote Expert Report) ¶ 255.)

Response to Finding No. 557

The proposed finding is vague because the terms "advanced adenoma," "nasopharyngeal carcinoma," "population diagnostic test," and "renal cell carcinoma" are undefined. This proposed finding is also misleading to the extent it is implying that InterVenn has an MCED test in development. The testimony from Mr. Leite and the InverVenn document Respondents cite indicate that InterVenn is developing multiple single cancer tests for use at different stages of cancer diagnoses and treatment. [redacted] Therefore, the Court should disregard the proposed finding.

a. InterVenn's VISTA™ proteomics platform

558. InterVenn currently provides an AI-enabled, mass spectrometry glycoproteomics based proteomics platform—not NGS—called VISTA. (RX3389 (InterVenn) at 1.) VISTA is a scalable platform to assess glycoprotein post-translational modifications in a site-specific manner across thousands of peptides and glycopeptides. (RX3869 (Cote Expert Report) ¶ 256.) It can quantify thousands of glycoproteoforms in a single measurement using only 10 microliters of serum/plasma. (RX3389 (InterVenn) at 1.)

Response to Finding No. 558

The proposed finding is improper, vague, and misleading. The proposed finding is

improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the second sentence of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 256; *see* Order on Post-Trial Findings at 3). And, moreover, this portion of Dr. Cote's report—i.e., the second sentence of the finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 256). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard the second sentence of Respondents' proposed finding.

The proposed finding is vague because the terms "proteomics," "glycoproteomics," "mass spectrometry," "post-translational," "peptides," "glycopeptides," and "glycoproteoforms" are undefined.

The proposed finding is also misleading and contrary to the weight of the evidence to the extent that respondents are implying that the InterVenn proteomics platform is somehow a substitute for NGS systems for multi-cancer screening. [redacted] Indeed, as noted in Complaint Counsel's response to Respondents Proposed finding No. 558 above, InterVenn appears to be developing single cancer tests and not MCED tests on its proteomics platform. Therefore, the Court should disregard the proposed finding.

559. The VISTA platform can be used to identify new cancer biomarkers. (RX3869 (Cote Expert Report) ¶ 256.) For example, using multienzyme digestion and glycopeptide enrichment, InterVenn simultaneously monitored the abundances of over 600 glycopeptides,

showing its potential for clinical deployment in the fields of cancer. (RX3424 (Li et al., 2019) at 1.)

Response to Finding No. 559

The proposed finding is improper, vague, and contains unreliable hearsay evidence, and should be disregarded as unsupported. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the first sentence of the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 256; *see* Order on Post-Trial Findings at 3). And, moreover, this portion of Dr. Cote's report—i.e., the first sentence of the finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 256). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard the first sentence of Respondents' proposed finding.

This proposed finding also contains unreliable hearsay evidence. Respondents cite a three-year-old journal article to represent the capabilities of InterVenn, not a document was produced by InterVenn. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by InterVenn, which Respondents offer for the truth. Nowhere in this journal article (RX3424) is it apparent that the results being discussed relate to InterVenn's current product. As such, it is not reliable evidence for InterVenn's capabilities or purported applications. Because this proposed finding improperly relies on an expert report for a factual proposition and unreliable hearsay evidence, this Court should disregard it as unsupported.

The proposed finding is also vague because the terms "multienzyme digestion,"

"glycopeptide enrichment," and "glycopeptides" are undefined, while the term "fields of cancer" is ambiguous. Additionally, the proposed finding does not specify which new cancer biomarkers the VISTA platform can identify. Therefore, the Court should disregard the proposed finding.

560. InterVenn has used VISTA to conduct oncology research in over a dozen different cancers, including ovarian, renal, lung, liver, prostate, pancreas, nasopharyngeal, and colorectal cancer and several others. (RX3388 (InterVenn) at 2.)

Response to Finding No. 560

The proposed finding is misleading and vague. The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 256). The proposed finding is vague because the terms "oncology research" and "several others" are ambiguous. Therefore, the Court should disregard the proposed finding.

561. In November 2020, InterVenn announced that its VISTA panel has demonstrated multi-indication performance in early cancer detection for different cancers with sensitivities and specificities consistently above 90 and as high as 98%. (RX3087 (BusinessWire) at 1; RX3869 (Cote Expert Report) ¶ 56.)

Response to Finding No. 561

The proposed finding is vague because the terms "multi-indication performance" and "different cancers" are ambiguous. Respondents do not specify how many cancers or which cancers the VISTA panel has demonstrated an ability to detect. Moreover, this proposed finding is misleading to the extent it implies that InterVenn is developing an MCED test. The Business Wire article Respondents cite makes clear that InterVenn is developing a series of single cancer tests that "can be deployed in a highly targeted fashion in individuals at high risk for a particular disease." (RX3087 (Business Wire) at 2 (InterVenn Biosciences Reports Results on Vista, Nov. 10, 2020)). Therefore, the Court should disregard the proposed finding.

b. InterVenn's Dawn™ Immuno-Oncology test

562. InterVenn currently provides a glycoproteomics-based clinical diagnostic test called Dawn™ to help physicians make the best possible choice for patient outcomes when deploying immuno-oncology therapies. (RX3387 (InterVenn) at 1.)

Response to Finding No. 562

The proposed finding is misleading and vague. The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 257). The proposed finding is vague because the terms "glycoproteomics" and "immuno-oncology" are undefined. Therefore, the Court should disregard the proposed finding.

563. InterVenn currently has data to support Dawn™ in pancreatic cancer, lung cancer, melanoma, and are working on other cancers. (RX3387 (InterVenn) at 2.)

Response to Finding No. 563

The proposed finding is misleading and vague. The proposed finding is misleading because it is not clear what the data shows Dawn can do in pancreatic cancer, lung cancer, and melanoma. For instance, it is not clear if the Dawn test is used to detect these cancers, to identify the best treatment option, or perform some other task associated with oncology care. Additionally, the finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 257).

The proposed finding is vague because the terms "glycoproteomics" and "immuno-oncology" are undefined. Therefore, the Court should disregard the proposed finding.

563.1 In a 181–sample case control study with 45 samples from patients with pancreatic ductal adenocarcinoma and 136 control samples, the Dawn pancreatic cancer screening test achieved sensitivity of 91% and specificity of 86%. (RX3403 (Kasi et al., 2020) at 1–2.)

Response to Finding No. 563.1

The proposed finding is misleading, vague, and contains unreliable hearsay evidence.

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 257). The proposed finding is vague because the term "pancreatic ductal adenocarcinoma" is undefined.

This proposed finding also contains unreliable hearsay evidence. Respondents cite a journal article to represent the capabilities of Dawn, not a document was produced by InterVenn. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by InterVenn, which Respondents offer for the truth. Nowhere in this journal article (RX3403) is it apparent that the results being discussed relate to InterVenn's current Dawn product. As such, it is not reliable evidence for Dawn's capabilities or purported applications. Therefore, the Court should disregard the proposed finding.

4. **Seer**

564. Seer, Inc. ("Seer") is a biotechnology company based in Redwood City, California. (RX3774 (Seer) at 1.) Seer has a proteomics platform—not NGS—that may be used to develop multi-cancer screening tests. (RX3869 (Cote Expert Report) ¶ 258.) Seer's subsidiary, PrognomIQ, is known to be developing early cancer detection tests. (RX3869 (Cote Expert Report) ¶ 258.)

Response to Finding No. 564

The proposed finding is improper, unreliable, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the second and third sentences, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 258; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Cote's expert opinions to support this portion of the proposed finding, in contravention of this Court's Order, and therefore this Court

should disregard the second and third sentences of Respondents' proposed finding.

[redacted]

Complaint Counsel objects to Respondents' misattribution of RX3774, a document of unknown provenance, to Seer as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document was not produced by Seer. Respondents elected not to pursue any form of discovery from Seer in this action. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by Seer, which Respondents offer for the truth and attribute to a party that did not testify in this proceeding. Given the inherent unreliable nature of the document, it lacks probative value (*see* Rule 4.43(b)). This court should disregard RX3774.

The proposed finding is vague because the term "proteomics platform" is undefined. Therefore, this Court should disregard the proposed finding.

a. Seer's ProteographTM proteomics platform

565. Seer is developing a ProteographTM automated workflow proteomics platform that combines its proprietary magnetic nanoparticles for highly parallel protein separation with

commonly used liquid chromatography-mass spectrometry (LC-MS) technology for efficient proteomic profiling. (RX1605 (Blume et al., 2020) at 1–14.)

Response to Finding No. 565

The proposed finding is misleading and vague. Respondents' citation to RX1605 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX1605 is a 14-page document, so Respondents' citation to pages 1-14 comprises the entire document. Thus, Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 259).

The proposed finding is vague because the terms "proteomics platform," "magnetic nanoparticles," "liquid chromatography-mass spectrometry," and "proteomic profiling" are undefined. Therefore, this Court should disregard the proposed finding.

> 565.1 The Proteograph platform allows for multiplexing of the protein markers using tandem mass tags (TMTs), thus increasing the throughput of proteomic detections. (RX1605 (Blume et al., 2020) at 1–14; RX3869 (Cote Expert Report) ¶ 259.)

Response to Finding No. 565.1

The proposed finding is improper and vague. Respondents' citation to RX1605 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on

Post-Trial Findings at 3). RX1605 is a 14-page document, so Respondents' citation to pages 1-14 comprises the entire document. Thus, Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The only other support that Respondents rely on for the proposed finding is Dr. Cote's expert report, which is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents improperly rely on Dr. Cote's report for support, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 259; *see* Order on Post-Trial Findings at 3). Therefore, this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "multiplexing," tandem mass tags (TMTs)," and "proteomic detections" are undefined.

566. Seer has used its Proteograph platform to detect over 2,000 proteins from blood plasma samples of healthy and non-small cell lung cancer patients in a cancer classification study, demonstrating the applicability of the Proteograph platform to early cancer screening. (RX1605 (Blume et al., 2020) at 1–14.)

Response to Finding No. 566

The proposed finding is misleading and vague. Respondents' citation to RX1605 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX1605 is a 14-page document, so Respondents' citation to pages 1-14 comprises the entire document. Thus, Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. The Court should disregard this

proposed evidence.

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 260).

The proposed finding is vague because it does not specify or explain how detecting over 2,000 proteins from blood plasma samples demonstrates the applicability of the "Proteograph platform" to early cancer screening. Additionally, the term "non-small cell" is undefined. Therefore, this Court should disregard the proposed finding.

> 566.1 In a 288 participant study with 125 lung cancer patients, 81 patients with comorbidity, and 82 health individuals, Seer's Proteograph platform was used to analyze 1779 plasma proteins and Seer identified clusters of proteins with at least 10 members that should differential behavior in lung cancer patients compared with healthy and comorbid individuals. (RX3632 (Siddiqui et al., 2020) at 1; RX3869 (Cote Expert Report) ¶ 260.)

Response to Finding No. 566.1

The proposed finding is vague and confusing because the phrase "should differential behavior" does not make sense. Additionally, the term "10 members" is ambiguous and undefined. It is unclear if "10 members" refers to clusters of proteins, participants of the study, or something else entirely. Therefore, this Court should disregard the proposed finding.

567. Seer currently does not have any clinical trials listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 261.)

Response to Finding No. 567

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 261; *see* Order on

Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 261). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

b. PrognomiQ

568. PrognomiQ is a subsidiary and a recent spin-off of Seer. (RX3869 (Cote Expert Report) ¶ 262.) It is also developing early cancer screening tests by combining rich proteomic information, obtainable using Seer's Proteograph platform, with genomic, metabolomic, and other health data. (RX3587 (PrognomiQ) at 2.) There are no details available publicly about PrognomiQ's technologies or plans. (RX3869 (Cote Expert Report) ¶ 262.)

Response to Finding No. 568

The proposed finding, which consists of language copied and pasted verbatim from Dr. Cote's report, is unsupported, improper, and vague. It is unsupported because RX3587, a document pulled from PrognomiQ's website, does not support the claim that PrognomiQ is developing early cancer screening tests using Seer's Proteograph platform. Although RX3587 acknowledges that PrognomiQ is "developing transformative test products that enable early disease detection and treatment," the document says nothing about cancer specifically. Additionally, RX3587 does not mention Seer's Proteograph platform.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the first and third sentences, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 262; *see* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Cote's expert opinions to

support this portion of the proposed finding, in contravention of this Court's Order, and therefore this Court should disregard the first and third sentences of Respondents' proposed finding.

The proposed finding is vague because the term "proteomics information" is undefined, and "genomic, metabolomic, and other health data" is ambiguous. Therefore, this Court should disregard the proposed finding.

569. PrognomiQ currently does not have any clinical trials listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 263.)

Response to Finding No. 569

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 263; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 263). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

5. **Somalogic**

570. Somalogic is a biotechnology company based in Boulder, Colorado. (RX3869 (Cote Expert Report) ¶ 264.) Somalogic has a proteomics platform—not NGS—that may be used to develop screening tests for multiple cancers. (RX3869 (Cote Expert Report) ¶ 264.) Somalogic is known to be developing an early cancer detection test for lung cancer. (RX3869 (Cote Expert Report) ¶ 264.)

Response to Finding No. 570

The proposed finding is improper, unreliable, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 264; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 264). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

The proposed finding is vague because the term "proteomics platform" is undefined.

Therefore, this Court should disregard the proposed finding.

571. Somalogic developed an aptamer-microarray based proteomics platform called SomaScan that can measure approximately 7,000 unique human protein analytes in small volumes of biological samples. (RX3651 (Somalogic) at 1–7.)

Response to Finding No. 571

The proposed finding is misleading, vague, and unreliable. It is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 265).

The proposed finding is vague because the terms "aptamer-microarray," "proteomics platform," and "protein analytes" are undefined. Additionally, the term "small volumes" is ambiguous.

Complaint Counsel also objects to the attribution of RX3651, a document of unknown provenance, to Somalogic, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document was not produced by Somalogic. Respondents elected not to pursue any form of discovery from Somalogic in this action. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by Somalogic, which Respondents offer for the truth and attribute to a party that did not testify in this proceeding. Given the inherent unreliable nature of the document, it lacks probative value (*see* Rule 4.43(b)). This court should disregard RX3651 and the proposed finding.

571.1 The SomaScan Platform uses a proprietary protein-capture reagents called SOMAmer® (Slow Off-rate Modified Aptamer) reagents, which consist of short single-stranded DNA sequences with hydrophobic modifications. (RX3869 (Cote Expert Report) ¶ 265.)

Response to Finding No. 571.1

The proposed finding is improper, unreliable, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions

that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 265; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 265). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

The proposed finding is vague because the terms "protein-capture reagents," "Slow Off-rate Modified Aptamer) reagents," and "hydrophobic modifications" are undefined. Therefore, this Court should disregard the proposed finding.

571.2 These chemical modifications facilitate the aptamer binding to proteins and enhance the specificity and affinity of protein-nucleic acid interactions. (RX3869 (Cote Expert Report) ¶ 265.) As a result, these modified aptamers can bind target proteins with specificity, and also be recognizable as nucleotide sequences by specific DNA hybridization probes. (RX3869 (Cote Expert Report) ¶ 265.)

Response to Finding No. 571.2

The proposed finding is improper, unreliable, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 265; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 265). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

[redacted]

The proposed finding is vague because the terms "aptamer," "protein-nucleic acid interactions," "nucleotide sequences," and "DNA hybridization probes" are undefined. Additionally, the opening phrase "these chemical modifications" are ambiguous. Respondents do not provide adequate context to infer what modifications are referred to. Therefore, this Court should disregard the proposed finding.

> 571.3 The SomaScan Platform measures the levels of target proteins by capturing them using these unique target-binding, fluorescent labeled aptamers, and then measures the corresponding aptamer concentrations using microarrays of complementary DNA probes. (RX3651 (Somalogic) at 1–7; (RX3869 (Cote Expert Report) ¶ 265.).)

Response to Finding No. 571.3

The proposed finding is unsupported, improper, vague, and unreliable. It is unclear how RX3651 provides any support for the proposed finding because the document does not mention "fluorescent labeled aptamers," "corresponding aptamer concentrations," or "complementary DNA probes." Complaint Counsel objects to the attribution of RX3651, a document of unknown provenance, to Somalogic, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document was not produced by Somalogic. Respondents elected not to pursue any form of discovery from Somalogic in this action. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by Somalogic, which Respondents offer for the truth and attribute to a party that did not testify in this proceeding. Given the inherent unreliable nature of the document, it lacks probative value (*see* Rule 4.43(b)). This court should disregard RX3651. Respondents' citation to RX3651 also contravenes this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity

that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3651 is a seven-page document, so Respondents' citation to pages 1-7 comprises the entire document. Thus, Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The only other support that Respondents rely on for the proposed finding is Dr. Cote's expert report, which is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents improperly rely on Dr. Cote's report for support, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 265; *see* Order on Post-Trial Findings at 3). Therefore, this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "target-binding, fluorescent labeled aptamers," "aptamer concentrations," and "complementary DNA probes" are undefined

572. As a highly multiplexed, sensitive, quantitative, and reproducible proteomic tool, the SomaScan platform is not only used for identification of relevant protein biomarkers relating to cancers, but also for biomarker detection and analysis. (RX3869 (Cote Expert Report) ¶ 266.)

Response to Finding No. 572

The proposed finding is improper, unreliable, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support the proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 266; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not

contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 266). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

572.1 For example, researchers at the Indiana University School of Medicine recently used the SomaScan platform to identify potential serum protein biomarkers and pathways for pancreatic cancer cachexia. (RX3471 (Narasimhan et al., 2020) at 1–23.)

Response to Finding No. 572.1

The proposed finding is misleading and vague. Respondents' citation to RX3471 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3471 is a 23-page document, so Respondents' citation to pages 1-23 comprises the entire document. Thus, Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 266).

The proposed finding is vague because the terms "the SomaScan platform," "serum protein biomarkers" and "cachexia" are undefined. Therefore, this Court should disregard the proposed finding.

572.2 Researchers at MIT used the SomaScan platform, in part, to identify a panel of prostate cancer proteases biomarkers. (RX3177 (Dudani et al., 2018) at 1–6.)

Response to Finding No. 572.2

The proposed finding is misleading and vague. Respondents' citation to RX3177 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3177 is a six-page document, so Respondents' citation to pages 1-6 comprises the entire document. Thus, Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. The Court should disregard this proposed evidence.

The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 266).

The proposed finding is vague because the terms "the SomaScan platform" and "proteases" are undefined and the phrase "in part" is ambiguous. Therefore, this Court should disregard the proposed finding.

572.3 Researchers in Germany also used the SomaScan platform to identify links between the recurrence of ovarian carcinoma and proteins released into the tumor microenvironment. (RX3229 (Finkernagel et al., 2019) at 1–2.)

Response to Finding No. 572.3

The proposed finding is misleading and vague. It is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 266). The proposed finding is vague because the terms "[r]esearchers in Germany," "the SomaScan platform," "to identify links" and "tumor microenvironment" are undefined. Therefore, this Court should disregard the proposed finding.

572.4 Researchers in the U.K. and Spain collaborated with Somalogic to use the SomaScan platform to analyze protein biomarkers isolated from exosomes in plasma and urine of prostate cancer patients. (RX3738 (Welton et al., 2016) at 1–2; RX3736 (Webber et al., 2014) at 1.)

Response to Finding No. 572.4

The proposed finding is misleading and vague. The proposed finding is misleading because Respondents fail to identify Dr. Cote's report as the source from which the entire finding was copied and pasted verbatim. (RX3869 (Cote Report) ¶ 266). The proposed finding is vague because the terms "[r]esearchers," "collaborated with," and "SomaScan platform" are undefined. Therefore, this Court should disregard the proposed finding.

573. Somalogic currently does not have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 267.)

Response to Finding No. 573

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding is a direct quote from Dr. Cote's expert report, and Respondents cite only to Dr. Cote's report to support this proposed finding, in contravention of this Court's Order. (RX3869 (Cote Report) ¶ 267; *see* Order on Post-Trial Findings at 3). And, moreover, the quoted portion of Dr. Cote's report—i.e., the entire proposed finding—does not contain any factual citation at all, as it originally appeared in Dr. Cote's report. (RX3869 (Cote Report) ¶ 267). Respondents improperly rely on Dr. Cote's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Cote's report, and therefore this Court should disregard Respondents' proposed finding.

IV. NGS COMPETITION

A. Current Players

1. **Illumina**

574. Illumina entered the sequencing market following its acquisition of Solexa in 2006 and its subsequent debut of its first instrument, the Genome Analyzer, in 2007. (PX0091 (Illumina) at 4; RX3407 (Kircher et al., 2010) at 5.) The Genome Analyzer was capable of simultaneously sequencing several million very short sequences (up to 26 nucleotides) in a single sequencing run. (RX3407 (Kircher et al., 2010).)

Response to Finding No. 574

Complaint Counsel objects to the proposed finding as misleading and unsupported because it suggests that Illumina, not Solexa, initially developed the Genome Analyzer NGS platform and brought it to market. Illumina only acquired Solexa in "November 2006" (PX0091 (Illumina) at 004 (Illumina, Source Book, August 2020)), and the Solexa sequencer then immediately launched in "early 2007" (RX3407 (Illumina) at 5 (Kircher et al., 2010)). Therefore, this Court should disregard the proposed finding.

574.1 Since the introduction of the Genome Analyzer, Illumina has significantly improved its NGS sequencers' capabilities. Initially, the length of the sequence reads were limited to 26 nucleotides because of steeply increasing sequencing errors as the reads became longer. (RX3407 (Kircher et al., 2010).)

Response to Finding No. 574.1

Complaint Counsel has no specific response to this proposed finding.

574.2 Within three years of its introduction, the Genome Analyzer was able to simultaneously sequence more than 200 million fragments per run and generate sequence reads of up to 100 nucleotides from each strand, generating more than 50 Gb of sequence output. (RX3407 (Kircher et al., 2010).)

Response to Finding No. 574.2

Complaint Counsel objects to the proposed finding as unsupported. The source cited (RX3407) does not provide that within three years of its introduction, the Genome Analyzer was able to generate more than 50 gigabases of total sequence output per run. It appears Respondents' counsel must have derived that figure by performing a calculation, incorrectly. In fact, sequencing 200 million fragments to a read length of 100 nucleotides each would only

generate 20 gigabases of total sequence output per run (or 40 gigabases if running in paired end mode to sequence each fragment in both directions). Therefore, this Court should disregard the proposed finding.

574.3 The Genome Analyzer was replaced in 2010 by the HiSeq sequencers, which were subsequently replaced by the NovaSeq sequencers. (RX3869 (Cote Expert Report) ¶ 276.)

Response to Finding No. 574.3

Complaint Counsel objects to the proposed finding because it constitutes improper expert opinion. This Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote in an attempt to establish a purported fact—that the original Solexa Genome Analyzer was replaced in 2010 by the Illumina HiSeq and then the NovaSeq—in contravention of this Court's Order. The Court should disregard this evidence and the proposed finding.

575. Illumina currently provides five classes of NGS sequencers based on the same sequencing-by-synthesis mechanism of action. The below chart shows each of the Illumina instruments and their current throughput:

Table 3

Instrument(s)	Throughput	Read Length	Run Time
iSeq	Simultaneous sequencing of 4 million DNA fragments	2x150 nucleotides to generate outputs of -1.2 Gb per run	8–19 hours
MiniSeq	Simultaneous sequencing of 8–25 million DNA fragments	2x150 nucleotides to generate outputs of -1.9 to -7.5 Gb per run.	4–24 hours
MiSeq	Simultaneous sequencing of 1–25 million DNA fragments	2x150 to 3x300 nucleotides to generate outputs of -300 Mbp to -15 Gb per run	10–56 hours
NextSeq 500	Simultaneous sequencing of 130– 400 million DNA fragments	2x150 nucleotides to generate outputs of - 40 to 120 Gb per run	15–29 hours

Instrument(s)	Throughput	Read Length	Run Time
NextSeq 550/550 Dx	Simultaneous sequencing of 130– 400 million DNA fragments	2x150 nucleotides to generate outputs of - 16.25 to 120 Gb per run	12–30 hours
NextSeq 2000	Simultaneous sequencing of 400 million to 1.2 billion DNA fragments	2x150 nucleotides to generate outputs of - 40 to 360 Gb per run	11–48 hours
HiSeq X (discontinued)	Simultaneous sequencing of 6 billion DNA fragments	2x150 nucleotides to generate outputs of -1600 to -1800 Gb per run	
NovaSeq 6000	Simultaneous sequencing of 800 million to 20 billion DNA fragments	2x150 to 2x250 nucleotides to generate outputs of -80 Gb to -6 Tb per run	13–45 hours
[redacted]	[redacted]	[redacted]	[redacted]

(RX3357 (Illumina) at 6–7; RX3354 (Illumina) RX3353 (Illumina,); RX3364 (Illumina); (RX3371 (Illumina); RX1600 (Illumina) at 19, 25); PX0091 (Illumina) at 11.)

Response to Finding No. 575

[redacted]

[redacted]

576. Illumina NGS sequencers are about 99.9% accurate (>87% of bases >Q30) in calling the correct base from the DNA sequence. (RX3368 (Illumina).)

Response to Finding No. 576

Complaint Counsel has no specific response to this proposed finding.

577. Illumina's improvements to its sequencing technology have driven down the cost of sequencing dramatically. Twenty years ago, the human genome project took the joint effort of more than 200 scientists 13 years and about $3 billion to read a single human genome of about 3 Gbs. (RX3113 (Hayden) at 1–2.)

Response to Finding No. 577

Complaint Counsel objects to the proposed finding because it is unsupported, in that it cites no source for the assertion that Illumina's improvements to its sequencing technology have driven down the cost of sequencing dramatically.

Complaint Counsel has no other specific response to this proposed finding.

577.1 When Illumina introduced the Genome Analyzer, the cost to sequence a full human genome was about $10 million, which dropped to about $200,000 in 2009. (RX3113 (Hayden) at 1; RX3370 (Illumina).)

Response to Finding No. 577.1

Complaint Counsel has no specific response to this proposed finding.

577.2 In January 2014, Illumina announced the achievement of $1000 genome with its introduction of the HiSeq X system at 30x coverage (about 100 Gbs). (RX3370 (Illumina).)

Response to Finding No. 577.2

Complaint Counsel has no specific response to this proposed finding.

577.3 In August 2020, Illumina announced the introduction of the $600 genome with the NovaSeqTM 6000 v1.5 Reagent Kit. (RX3355 (Illumina).)

Response to Finding No. 577.3

Complaint Counsel has no specific response to this proposed finding.

577.4 [redacted]

Response to Finding No. 577.4

[redacted]

[redacted]

[redacted]

2. **Thermo Fisher**

578. Thermo Fisher Scientific, based in Waltham, Massachusetts, offers the Ion Torrent line of NGS platforms. (RX2577 (Thermo Fisher) at 1.) Thermo Fisher inherited the Ion Torrent brand via its merger with Life Technologies and Life's prior acquisition of Ion Torrent Systems Inc. (PX7070 (Felton (Thermo Fisher) IHT at 11.) Ion Torrent Systems Inc. developed and released the Ion Torrent NGS sequencers in 2010. (PX2482 (Thermo Fisher) at 50.)

Response to Finding No. 578

Complaint Counsel has no specific response to the proposed finding.

578.1 As with the Illumina sequencers, the nucleic acids to be sequenced must undergo sample preparation before sequencing. (RX3869 (Cote Expert Report) ¶ 281.) The DNA fragments are attached to microscopic beads and the fragments undergo amplification using PCR so that each bead is covered with many copies of the fragment to be sequenced. (RX3869 (Cote Expert Report) ¶ 281.) Each time a nucleotide is incorporated into the sequence (e.g., for the sequencing by synthesis), a hydrogen ion is released. (RX3690 (Thermo Fisher) at 2–3.)

Response to Finding No. 578.1

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony, is misleading, and is against the weight of the evidence.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support purported basic facts about Thermo Fisher Ion Torrent sequencers, in contravention of this Court's Order. This Court should disregard this evidence.

The proposed finding is misleading to the extent that "[a]s with Illumina sequencers" suggests sample preparation for Thermo Fisher's instruments is related to or interchangeable

with sample preparation for Illumina instruments. The proposed finding is also misleading to the extent it implies that Thermo Fischer Scientific's NGS platform is interchangeable with Illumina's NGS platforms.

[redacted] Therefore, this Court should disregard the proposed finding.

578.2 The Ion Torrent sequencers use semiconductors to measure the pH change resulting from the release of hydrogen ions during the incorporation reaction to identify the nucleotides in the sample being sequenced. (RX3690 (Thermo Fisher) at 3.)

Response to Finding No. 578.2

Complaint Counsel has no specific response to the proposed finding.

579. Thermo Fisher currently markets four Ion Torrent NGS systems: the Ion PGM Dx System, the Ion Proton System, the Ion GeneStudio S5 Systems, and the Ion Torrent Genexus System. The below chart shows each of the Thermo Fisher instruments and their current throughput:

Table 4

Instrument(s)	Throughput	Read Length	Run Time
Ion PGM Dx	Simultaneous sequencing of 4 to 5.5 million DNA fragments	200 nucleotides to generate outputs of ~ 0.6 to ~1 Gb per run	4.4 hours
Ion Proton	Simultaneous sequencing of ~ 60 to 80 million DNA fragments	200 nucleotides to generate outputs of up to 15 Gb per run	~2.5 hours
Ion GeneStudio S5	Simultaneous sequencing of ~ 2 to 130 million DNA fragments	200 to 600 nucleotides to generate outputs of ~ 0.3 to 50 Gb per run	~3 to 12 hours
Ion Torrent Genexus	Simultaneous sequencing of ~ 48 to 60 million DNA fragments	200 to 400 nucleotides to generate outputs of 10 to 12 Gb per run	12 hours

(RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher).)

Response to Finding No. 579

Complaint Counsel objects to the proposed finding as unsupported because the source cited (RX3685) that discusses the Ion Torrent Genexus sequencer does not provide that the run time of the instrument is "12 hours." Complaint Counsel does not disagree with the remainder of the proposed finding.

580. The Ion Torrent NGS sequencers are about 98.4–99.2% accurate (>Q20) in calling the correct base from the DNA sequence. (RX3693 (Thermo Fisher).) Thermo Fisher's Ion Torrent sequencers' run time is typically less than 12 hours, comparable to Illumina's 11–45 hours run time for the NextSeq and NovaSeq NGS sequencers. (RX3869 (Cote Expert Report) ¶ 282.)

Response to Finding No. 580

Complaint Counsel objects to the proposed finding because it is unsupported, incorrect, misleading, and constitutes improper expert opinion.

The proposed finding claims the Ion Torrent NGS sequencers are "about 98.4-99.2% accurate" and characterizes that accuracy range as ">Q20," which is incorrect. The source cited (RX3693)—a 36-page document to which Respondents do not provide a specific page cite, in contravention of this Court's Post-Trial Order, which explicitly requires that all facts be supported by "specific references to the evidentiary record" (*see* Order on Post-Trial Findings at 2)—does not characterize this accuracy range as ">Q20." Respondents' counsel must have added the ">Q20" descriptor, without understanding precisely what it means or that it is incorrect. In fact, Q20 means 99% accuracy. (*See, e.g.*, RX3541 (Oxford Nanopore) at 2 (Oxford Nanopore Tech Update, May 21, 2021) (explaining that its "Q20+" chemistry generates >99% accuracy)). The purported accuracy range of "about 98.4-99.2" for Thermo Fisher Ion Torrent sequencers, therefore, dips substantially below Q20.

This Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote in an attempt to establish purported facts—the run times of Thermo

Fisher and Illumina sequencers—in contravention of this Court's Order. The Court should disregard this evidence and disregard the proposed finding as unsupported.

The proposed finding is misleading because it compares only the run times between the Thermo Fisher Ion Torrent sequencers and Illumina NextSeq and NovaSeq sequencers, divorced from the number of reads, accuracy, and cost of the respective runs. [redacted]

Therefore, this Court should disregard the proposed finding.

581. Thermo Fisher's Ion GeneStudio S5 Systems are also equipped to perform three types of genome-wide methylation profiling strategies: (i) bisulfite conversion; (ii) enzymatic genomic partition to separate the genome into methylated and unmethylated compartments with methylation-sensitive restriction enzymes, thus allowing more sensitive detection of DNA methylation through NGS sequencing; and (iii) enrichment of methylated DNA using affinity purification of methylated genomic DNA fragments, thus similarly allowing more sensitive detection of DNA methylation through NGS sequencing. (RX3691 (Thermo Fisher).)

Response to Finding No. 581

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence.

The proposed finding's use of "more sensitive detection" is vague because it does not specific what it is purportedly more sensitive than.

The proposed finding is misleading to the extent that it suggests Thermo Fisher's Ion GeneStudio S5 system is in any way unique in its capability to sequence DNA samples that have undergone bisulfite conversion, enzymatic genomic partitioning, or enrichment of methylated DNA to preserve methylation status. Nothing in the source cited (RX3691), which purports to be a capture of a page from Thermo Fisher's website, states that Thermo Fisher has any unique or proprietary capability in this regard.

The proposed finding is also misleading to the extent that it suggests Thermo Fisher's Ion GeneStudio S5 system can be used for MCED testing. Nothing in the source cited (RX3691), which purports to be a capture of a page from Thermo Fisher's website, mentions MCED testing or even any liquid biopsy application.

The proposed finding is also misleading to the extent it implies that Thermo Fischer Scientific's NGS platform is interchangeable with Illumina's NGS platforms. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

581.1 Thermo Fisher also offers chromatin immunoprecipitation sequencing ("ChIP-Seq") for its Ion Torrent sequencers. (RX3680 (Thermo Fisher).)

Response to Finding No. 581.1

Complaint Counsel objects to the proposed finding because it is misleading.

The proposed finding is misleading to the extent it suggests Thermo Fisher's Ion Torrent sequencers can be used for MCED testing. Nothing in the source cited (RX3680), which purports to be a capture of a page from Thermo Fisher's website, mentions MCED testing or even any liquid biopsy application.

The proposed finding is also misleading to the extent it implies that Thermo Fischer Scientific's NGS platform is interchangeable with Illumina's NGS platforms. [redacted]

Therefore, this Court should disregard the proposed finding.

581.2 Researchers have also developed protocols to perform methylated DNA immunoprecipitation sequencing ("MeDIP-Seq") using Thermo Fisher's Ion Torrent sequencers; MeDIP Seq may be used to study DNA methylation genome-wide. (RX3158 (Corley et al., 2015).)

Response to Finding No. 581.2

Complaint Counsel objects to the proposed finding because it is misleading.

The proposed finding is misleading to the extent it suggests Thermo Fisher's Ion Torrent sequencers can be used for MCED testing. Nothing in the research paper cited (RX3158), which Respondents cite with no additional context, mentions MCED testing or even any liquid biopsy application.

The proposed finding is also misleading to the extent it implies that Thermo Fischer Scientific's NGS platform is interchangeable with Illumina's NGS platforms. [redacted]

Therefore, this Court should disregard the proposed finding.

582. Thermo Fisher's share of the clinical oncology segment has increased over the last five years. (PX7097 (Felton (Thermo Fisher) Dep. at 91).) [redacted]

Response to Finding No. 582

[redacted]

[redacted]

583. [redacted]

Response to Finding No. 583

[redacted]

[redacted]

584. Thermo Fisher will offer its solutions to MCED test developers and agrees that its sequencers are capable of being used for multi-cancer screening tests, and researchers are successfully developing new ways to use Thermo Fisher products for early cancer screening applications. (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).)

Response to Finding No. 584

[redacted]

[redacted]

585. Even though the technical parameters of Thermo Fisher's Ion Torrent platform may be inferior to Illumina's high-end sequencers, the Ion Torrent sequencers are nonetheless suitable for certain multi-cancer screening tests. (RX3869 (Cote Expert Report) ¶ 285.)

Response to Finding No. 585

Complaint Counsel objects to the proposed finding because it is vague, relies solely on self-serving expert opinion testimony, is unsupported, and is against the weight of the evidence.

The proposed finding is vague because it does define or quantify what technically

"inferior" means, nor what "suitable" means, nor list which MCED tests are the "certain" ones for which the technically inferior Thermo Fisher Ion Torrent NGS platform is nonetheless suitable.

[redacted] From this Dr. Cote somehow generates the internally inconsistent, vague conclusion that, despite technical inferiority to Illumina, Thermo Fisher's Ion Torrent sequencer is "suitable" for "certain" (unidentified) MCED tests. This opinion contains no true expert analysis and is merely an empty black box entitled to no weight.

[redacted]

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

586. If a test developer came to Thermo Fisher and wanted to reconfigure its assay to run on Thermo Fisher's platforms, Thermo Fisher would assist in putting the test onto its platform. (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 143–44).)

Response to Finding No. 586

[redacted]

586.1 [redacted]

Response to Finding No. 586.1

[redacted]

586.2 [redacted]

Response to Finding No. 586.2

[redacted]

[redacted]

3. **BGI**

587. BGI Genomics, formerly known as the Beijing Genomics Institute, is a Chinese genome sequencing company. (RX3060 (BGI) at 1.) It acquired California-based sequencing company Complete Genomics in 2013 and launched its BGISEQ-500 NGS sequencer in 2015 based on Complete Genomics' core technology. (RX3063 (BGI).)

Response to Finding No. 587

Complaint Counsel objects to the proposed finding because it misattributes the source of documents and is unsupported, incomplete, and misleading.

Complaint Counsel objects to the attribution of RX3060 (a news article *about* BGI, not a BGI document) and RX3063 (which Respondents purportedly captured from BGI's website at a now-broken URL) to BGI as the source of the documents, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from BGI in this action, likely because they know such evidence would not support their contention that BGI will be a feasible alternative NGS platform available to MCED developers in the United States any time in the foreseeable future. Indeed, Illumina has obtained discovery from BGI on this very topic in another proceeding, prompting the court to conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v.*

BGI Genomics Co., Ltd., No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022) (noting the deposition testimony of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

The proposed finding is unsupported because the source cited (RX3063) does not provide that Complete Genomics was based in California or that BGI acquired Complete Genomics in 2013.

The proposed finding is incomplete because BGI is not merely a Chinese genome sequencing company, but rather "it is closely linked to the Chinese government," it "runs a massive gene databank in China," and "U.S. security officials have warned American labs against using Chinese tests for COVID-19 because of concern China was seeking to gather foreign genetic data for its own research." (RX3060 at 1; *see also* deSouza (Illumina) Tr. 2312 ("[BGI is] sponsored by the Chinese government or affiliated with the Chinese government").)

The proposed finding is misleading to the extent it suggests that BGI has ever launched or sold any NGS platform in the United States. The source cited indicates only that the BGISEQ500 sequencer was "available in China." (RX3063 at 2.) In fact, BGI platforms have never been sold in the United States, due in large part to injunctions Illumina has obtained against BGI in patent infringement suits. (*See* CCFF ¶¶ 1269-75.) Illumina is seeking additional injunctive relief against BGI in federal court based on U.S. patents that do not expire until as late as 2027. (*See* CCFF ¶¶ 1276-85.) Therefore, this Court should disregard the proposed finding.

588. BGI's NGS sequencers use an SBS technology that is similar to Illumina's NGS sequencing technology. (RX3869 (Cote Expert Report) ¶ 286.)

Response to Finding No. 588

Complaint Counsel objects to the proposed finding because it constitutes improper expert opinion and is misleading.

This Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote in an attempt to establish a purported fact—that BGI sequencers use an SBS technology similar to Illumina's—in contravention of this Court's Order. The Court should disregard this evidence.

The proposed finding is misleading because it suggests that BGI sequencers perform similarly to Illumina sequencers. [redacted] Therefore, this Court should disregard the proposed finding.

588.1 BGI is currently enjoined from launching its sequencing instruments and related reagents in the United States due to its infringement of a certain Illumina patents that expire in 2022 and 2023. (RX3356 (Businesswire).)

Response to Finding No. 588.1

Complaint Counsel objects to the proposed finding because it is incomplete and misleading in that it suggests Illumina is seeking injunctive relief against BGI based only on patents that expire in 2022 and 2023. In fact, Illumina is seeking additional injunctive relief against BGI in federal court based on U.S. patents that do not expire until as late as 2027. (*See* CCFF ¶¶ 1276-79, 82-83.)

Complaint Counsel does not disagree that to date one federal court has already found that BGI infringed multiple Illumina patents.

588.2 BGI may enter the U.S. market by August 2022. *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the

> patents-in-suit—as they are permitted—they must include the following conspicuous written disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'").

Response to Finding No. 588.2

Complaint Counsel objects to the proposed finding because it is unsupported, incomplete, and misleading.

The proposed finding is unsupported in that the court order cited does not provide that "BGI may enter the U.S. market by August 2022." The court order *bars* BGI from entering until after August 23, 2022, but it in no way purports to authorize or permit BGI to "enter the U.S. market" as of that date, nor could it. The federal court in the Northern District of California ruled solely on the case or controversy before it, which involved the limited set of U.S. patents Illumina chose to assert *in that lawsuit only*. The court determined nothing whatsoever regarding other patents, lawsuits, or other legal obstacles that may well block BGI from entering the U.S. market long after August 23, 2022.

The proposed finding is incomplete and misleading in that it suggests Illumina is only seeking injunctive relief against BGI through the suit captioned *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal.), in federal court in the Northern District of California. In fact, Illumina is already seeking additional injunctive relief against BGI in federal court in the District of Delaware in the suit captioned *Complete Genomics, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.), based on patents that do not expire until as late as 2027. (*See* CCFF ¶¶ 1276-79, 82; PX9232 at 015, 025-027 (Answer and Counterclaim, *Complete Genomics, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019); deSouza (Illumina) Tr. 2227). Moreover, Illumina holds additional patents touching "every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina's significant investments in research and

development" that extend to beyond 2030 and which "may become relevant" against BGI. (deSouza (Illumina) Tr. 2231-2232; PX2822 (Illumina) at 006-007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)). Therefore, this Court should disregard the proposed finding.

589. BGI's technology also measures the light emission when a fluorescent labeled base is incorporated into the DNA strand. (RX3065 (BGI).) BGI recently introduced a CoolMPSTM (Massively Parallel Sequencing) technology that measures the light emission when a fluorescently-labeled antibody specifically binds to the base that has been incorporated into the DNA strand. (RX3175 (Drmanac et al., 2020).)

Response to Finding No. 589

Complaint Counsel objects to the proposed finding because it misattributes the source of a document and is unsupported, confusing, and vague.

Complaint Counsel objects to the attribution of RX3065 to BGI as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. RX3065 appears to be a document from BGI, but it is unclear how, when, and from where Respondents obtained the document. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from BGI in this action, likely because they know such evidence would not support their contention that BGI will be a feasible alternative NGS platform available to MCED developers in the United States any time in the foreseeable future. Indeed, Illumina has obtained discovery from BGI on this very topic in another proceeding, prompting the court to conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022) (noting the deposition testimony of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

The proposed finding is unsupported because RX3065 does not say that "BGI's

technology also measures the light emission when a fluorescent labeled base is incorporated into the DNA strand" or even discuss incorporation of DNA bases or light emission. (RX3065.)

The proposed finding is unsupported and confusing because the source cited (RX3065) describes a BGI sequencing service offering, not BGI instruments sold to and operated by individual laboratories, and it is unclear to what extent, if any, the information applies to BGI instruments that were ever sold or offered for sale to independent laboratories.

The proposed finding is vague because it does not define what it means for BGI to have purportedly "introduced" CoolMPS™ technology. The proposed finding is unsupported because the unpublished, non-peer reviewed paper by Drmanac et al. that is cited does not describe any type of commercial launch of the technology but rather explains that CoolMPS™ chemistry is "still at the beginning of the development cycle." (RX3175 at 11, 16.). Therefore, this Court should disregard the proposed finding.

590. BGI currently markets five sequencers. The below chart shows each of the BGI instruments and their current throughput:

Table 5

Instrument(s)	Throughput	Read Length	Run Time
DNBSEQ-G50	Simultaneous sequencing of ~ 100 to 500 million DNA fragments	50 to 2x150 nucleotides to generate outputs of up to ~ 150 Gb per run	10–66 hours
DNBSEQ-G400 FAST	Simultaneous sequencing of ~ 550 million DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 330 Gb per run	13–37 hours
DNBSEQ-G400	Simultaneous sequencing of ~ 1,500 to 1,800 million DNA fragments	50 to 2x200 nucleotides to generate outputs of up to 1,440 Gb (1.44 Tb) per run	13–37 hours
DNBSEQ-T7	Simultaneous sequencing of ~ 20 billion DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 6,000 Gb (6 Tb) per run	<24 hours
DNBSEQ-T10×4RS / DNBSEQ-Tx	Simultaneous sequencing of ~ 80 billion DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 20 Tb per day	<24 hours

(RX3465 (MGI Tech); RX4004 (MGI Tech).)

Response to Finding No. 590

Complaint Counsel objects to the proposed finding because it misattributes the source of a document and is vague, confusing, unsupported, and misleading.

Complaint Counsel objects to the attribution of RX4004 to MGI Tech. (an affiliate of BGI) as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. RX4004 appears to be a press release from MGI, but it is printed from a third-party website, and it is unclear whether it has been translated or whether any pictures, including potentially relevant pictures of the DNBSEQ-T10x4RS instrument discussed in the press release, have been omitted (the first page of the exhibit shows a broken image icon). Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from BGI in this action, likely because they know such evidence would not support their contention that BGI will be a feasible alternative NGS platform available to MCED developers in the United States any time in the foreseeable future. Indeed, Illumina has obtained discovery from BGI on this very topic in another proceeding, prompting the court to conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022) (noting the deposition testimony of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

The proposed finding is vague because it does not make clear that the figures provided in the "Throughput" column refer to the number of fragments that can be sequenced simultaneously per run of the instrument, not per flow cell within each run.

The proposed finding is confusing and misleading because, underneath the "Read

Length" column, it also provides the total output of each instrument run in bases (gigabases or terabases). The total output in bases of a sequencer per run of the instrument (or per period of time) is an irrelevant metric for the application of MCED tests. [redacted]

The proposed finding is unsupported because neither of the cited sources (RX3465 or RX4004) provides any of the metrics listed in the table for the DNBSEQ-G400 FAST sequencer.

The proposed finding is misleading because it claims a run time of "13-37 hours" for the DNBSEQ-G400, but the source cited (RX3465) indicates that short run time only applies when using the small flow cell ("FCS"). (RX3465 at 2.) The run time when using the large flow cell ("FCL"), which would be necessary to realize the "simultaneous sequencing of 1,500 to 1,800 million DNA fragments" claimed in the table, is 14~109 hours. (RX3465 at 2.)

The proposed finding is incomplete because it omits the fact that the DNBSEQ-T7 is only capable of reading "5000M" (5 billion) fragments per flow cell (RX3465 at 2) and presumably must then need to process four flow cells per run to achieve the purported throughput of simultaneously sequencing 20 billion fragments per run.

The proposed finding is unsupported because neither of the cited sources (RX3465 or RX4004) provides that the DNBSEQ-T10x4RS is capable of simultaneous sequencing of ~ 80 billion DNA fragments. The proposed finding is also unsupported because neither of the cited

sources (RX3465 or RX4004) mentions a "DNBSEQ-Tx" sequencer model.

The proposed finding is misleading because it does not clarify that the DNBSEQ-T10x4RS is not a single instrument but is instead a cluster of four large sequencing machines. Although pictures of the DNBSEQ-T10x4RS instrument (or rather instruments) may have been omitted from RX4004, the document refers to "set" of DNBSEQ-T10x4RS (RX4004 at 1), and the fact that the model name contains "x4" further confirms that the DNBSEQ-T10x4RS is a package configuration of four instrument units, with four times the footprint (and possibly four times the price). Evaluating a four-instrument BGI installation against a single Illumina NovaSeq or Lightning instrument is not an apples-to-apples comparison. Therefore, this Court should disregard the proposed finding.

591. BGI's DNBSEQ sequencer's reported accuracy is comparable to Illumina's sequencers, and guarantees more than 80% of bases with a quality score greater than Q30—which is over 99.9% accurate. (RX3465 (MGI Tech); RX3067 (BGI).)

Response to Finding No. 591

Complaint Counsel objects to the proposed finding because it misattributes the source of a document and is unsupported, misleading, and against the weight of the evidence.

Complaint Counsel objects to the attribution of RX3067 to BGI as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. RX3067 appears to be a document from BGI, but it is unclear how, when, and from where Respondents obtained the document. (RX3067.) Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from BGI in this action, likely because they know such evidence would not support their contention that BGI will be a feasible alternative NGS platform available to MCED developers in the United States any time in the foreseeable future. Indeed, Illumina has obtained discovery from BGI on this very topic in another proceeding, prompting the court to

conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022) (noting the deposition testimony of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

The proposed finding is unsupported because neither of the sources cited provides that BGI's DNBSEQ sequencers' reported accuracy is comparable to Illumina's sequencers. In fact, neither source cited even mentions Illumina sequencers (RX3067 only mentions Illumina microarray products).

The proposed finding is misleading because RX3067 describes a BGI sequencing *service* offering, not BGI instruments sold to and operated by individual laboratories, and it is unclear to what extent, if any, the information applies to BGI instruments that were ever sold or offered for sale to independent laboratories. (RX3067.)

The proposed finding is against the weight of substantial evidence showing that BGI sequencers do not perform similarly to Illumina sequencers. [redacted] Therefore, this Court should disregard the proposed finding.

592. BGI's highest throughput instrument has a higher reported throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run), [redacted] (*Compare* RX4004 (MGI Tech) at 1–2 *with* RX3357 (Illumina) at 7; [redacted]

Response to Finding No. 592

[redacted]

[redacted]

593. BGI/MGI offers the MGIEasy Whole Genome Bisulfite Sequencing Library Prep Kit for DNA methylation analysis using bisulfite conversion. (RX3465 (MGI Tech).) BGI also provide whole-genome bisulfite sequencing and target region bisulfite sequencing for either genome-wide DNA methylations profiling or DNA methylations profiling in specific regions of interest. (RX3070 (BGI).)

Response to Finding No. 593

Complaint Counsel objects to the proposed finding because it is unsupported and misleading.

The proposed finding is unsupported because the first source cited (RX3465) does not reference an "MGIEasy Whole Genome Bisulfite Sequencing Library Prep Kit" or contain any information whatsoever about bisulfite sequencing or methylation analysis. The proposed finding is unsupported because the second source cited (RX3070) only discusses "whole genome" bisulfite sequencing but makes no mention of "target region" bisulfite sequencing.

The proposed finding is misleading because RX3070 describes a BGI sequencing *service* offering, not BGI instruments sold to and operated by individual laboratories, and it is unclear to what extent, if any, the information applies to BGI instruments that were ever sold or offered for sale to independent laboratories. The proposed finding is also confusing because RX3070 provides general background information about whole genome bisulfite sequencing but does not say that BGI offers bisulfite sequencing. Therefore, this Court should disregard the proposed finding.

593.1 BGI also offers ChIP-Seq services to analyze protein interaction with DNA using its DNBSEQ sequencers. (RX3066 (BGI).) Sequencers capable of sequencing DNA that has been prepared using chromatin immunoprecipitation (ChIP) are also capable of sequencing DNA that has been prepared using methylated-DNA immunoprecipitation (MeDIP).

Response to Finding No. 593.1

Complaint Counsel objects to the proposed finding because it is misleading and unsupported.

The proposed finding is misleading because RX3066 describes a BGI sequencing *service* offering, not BGI instruments sold to and operated by individual laboratories, and it is unclear to what extent, if any, the information applies to BGI instruments that were ever sold or offered for sale to independent laboratories.

The proposed finding is unsupported because it does not cite to any evidence of record for the point that sequencers capable of sequencing DNA that has been prepared using chromatin immunoprecipitation (ChIP) are also capable of sequencing DNA that has been prepared using methylated-DNA immunoprecipitation (nor does RX3066 support the point). Therefore, this Court should disregard the proposed finding.

594. BGI's reported sequencing costs for its DNBSEQ sequencers are lower than those for Illumina's NovaSeq instrument.

Response to Finding No. 594

Complaint Counsel object to the proposed finding because it is unsupported, as it does not cite to any evidence of record. Therefore, this Court should disregard the proposed finding.

594.1 For example, BGI advertises Whole Genome Sequencing service for $400 in the U.S. and worldwide on the DNBSEQ platforms, at about $4 per Gb. (RX3068 (BGI); RX3071 (BGI).)

Response to Finding No. 594.1

Complaint Counsel objects to the proposed finding because it is misleading in that the

sources cited (RX3068 and RX3071) describe a BGI sequencing *service* offering, not BGI instruments sold to and operated by individual customers or laboratories at their own sites, which is what this case is about. Moreover, the service described (whole genome sequencing) is not the application at issue in this case (sequencing of cfDNA for MCED testing). There is no basis for applying information contained in RX3068 or RX3071 about the price of BGI's irrelevant in-house service offering to imagined commercial sales of unidentified BGI instruments and consumables for an altogether different application. Therefore, this Court should disregard the proposed finding.

> 594.2 BGI also announced that its DNBSEQ-T10×4RS sequencers can generate $100 genomes, making it per Gb cost only $1.00. (RX4004 (MGI); *see also* deSouza (Illumina) Tr. 2331 ("Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world").

Response to Finding No. 594.2

Complaint Counsel objects to the proposed finding because it misattributes the source of a document and is unsupported and misleading.

Complaint Counsel objects to the attribution of RX4004 to MGI Tech. (an affiliate of BGI) as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. RX4004 appears to be a press release from MGI, but it is printed from a third-party website, and it is unclear whether it has been translated or whether any pictures, including potentially relevant pictures of the DNBSEQ-T10x4RS instrument discussed in the press release, have been omitted (the first page of the exhibit shows a broken image icon). Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from BGI in this action, likely because they know such evidence would not support their contention that BGI will be a feasible alternative NGS platform available to MCED developers in the United States any time in

the foreseeable future. Indeed, Illumina has obtained discovery from BGI on this very topic in another proceeding, prompting the court to conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022) (noting the deposition testimony of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

The proposed finding is unsupported because the source cited (RX4004) does not say that the DNBSEQ-T10x4RS sequencers can "generate $100 genomes" or that the per gigabase cost is only $1, nor does it contain any figures whatsoever relating to the cost of sequencing.

The proposed finding is misleading because it does not clarify that the DNBSEQ-T10x4RS is not a single instrument but is instead a cluster of four large sequencing machines. Although pictures of the DNBSEQ-T10x4RS instrument (or rather instruments) may have been omitted from RX4004, the document refers to "set" of DNBSEQ-T10x4RS (RX4004 at 1), and the fact that the model name contains "x4" further confirms that the DNBSEQ-T10x4RS is a package configuration of four instrument units, with four times the footprint (and possibly four times the price). Evaluating a four-instrument BGI installation against a single Illumina NovaSeq or Lightning instrument is not an apples-to-apples comparison. Therefore, this Court should disregard the proposed finding.

595. [redacted]

Response to Finding No. 595

[redacted]

[redacted]

595.1 [redacted]

Response to Finding No. 595.1

[redacted]

595.1.1 [redacted]

Response to Finding No. 595.1.1

[redacted]

[redacted]

[redacted]

4. **GenapSys**

596. GenapSys, Inc., based in Redwood City, California, launched its GenapSys Sequencer in 2019. (RX3402 (GenomeWeb).) This new NGS sequencing platform uses semiconductors to measure the minute impedance change, i.e., the change in the effective resistance of the reaction solution, resulting from the incorporation reaction. (RX3257 (GenapSys).) GenapSys's technology also relies on a sequencing-by-synthesis approach. (RX3869 (Cote Expert Report) ¶ 290.)

Response to Finding No. 596

Complaint Counsel objects to the proposed finding because it misattributes the source of a document, relies on hearsay evidence, and improperly cites expert testimony.

Complaint Counsel objects to the attribution of RX3257 (which Respondents purportedly captured from Genapsys's website at a now-broken URL) to Genapsys as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document constitutes hearsay. The proposed finding also cites RX3402, a stale GenomeWeb article from 2019 that also constitutes hearsay. Given the inherent unreliable nature of these documents, they have little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from Genapsys in this action, likely because they know such evidence would not support their contention that Genapsys is a feasible alternative NGS platform available for MCED developers.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support facts, in contravention of this Court's Order. This Court should disregard this evidence and the proposed finding.

597. GenapSys' NGS sequencer has comparably low costs for both the equipment and per run cost. Reports suggest that the list price of the GenapSys Sequencer is only $9,900 and a

sequencing kit for a 16 MM chip single run costs $299. (RX3262 (GenomeWeb).) GenapSys announced in January 2021 that the cost on its 144 MM chip to be shipped this year would be about $27 per Gb. (RX3732 (Vilella).)

Response to Finding No. 597

Complaint Counsel objects to the proposed finding because it is misleading, unreliable, unsupported, against the weight of the evidence, and vague.

The proposed finding is misleading because it suggests that Genapsys sells a 144 MM sequencing chip but cites no reliable source for that claim. First, it cites a stale hearsay article from November 2019 reporting that "the 144 million sensor chip will be available next year" (i.e., 2020). (RX3262 at 1). Then it cites RX3732, which is even less reliable hearsay—a Twitter feed from a person named "Albert Vilella" of unknown affiliation or credentials, who did not testify in this proceeding—claiming in January 2021 that "[t]hey now are aiming at 2021 to ship two new chips: 50MM read chip and 144MM sensor chip (not sure what the difference is between read/sensor)." (RX3732 at 1). But the proposed finding cites no evidence that Genapsys ever actually commercially shipped a 144 MM chip, as opposed to merely announcing plans to do so (and then failing to meet the announced target). Indeed, Respondents elected not to pursue any form of discovery from Genapsys in this action, likely because they know such evidence would not support their contention that Genapsys is a feasible alternative NGS platform available for MCED developers.

The proposed finding is misleading and against the weight of the evidence to the extent it suggests that any purported Genapsys sequencer is a viable platform for MCED testing. The proposed finding is against the weight of the evidence from [redacted]

[redacted]

The proposed finding is vague because it claims "GenapSys' NGS sequencer has comparably low costs for both the equipment and per run cost" but does not explain what it is being compared to. Therefore, this Court should disregard the proposed finding.

5. **Oxford Nanopore**

598. Oxford Nanopore Technology ("ONT") is a spin-out from the University of Oxford that launched in 2005. (RX3538 (ONT) at 1–3.) ONT's nanopore sequencing technology measures the minute change in electrical conductance across biological nanopores when DNA molecules thread through those nanopores under the control of enzyme motors, using nanopore sensors with the ability to differentiate nucleotides. (RX3538 (ONT); RX3166 (Deamer et al., 2016).)

Response to Finding No. 598

Complaint Counsel objects to the proposed finding because it misattributes the source of documents.

Complaint Counsel objects to the attribution of RX3538, which Respondents purportedly captured from ONT's website—to ONT as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

Complaint Counsel also objects to the attribution of RX3166—which appears to be a non-final author manuscript by Deamer et al., and which Respondents to not explain how they obtained—to ONT as the source of the document, in contravention of this Court's Order. *See*

Order on Post-Trial Findings at 3. Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers. Therefore, this Court should disregard the proposed finding.

599. ONT currently makes four NGS sequencers, with one more in development. The below chart shows each of the ONT instruments and their current throughput:

Table 6

Instrument(s)	Throughput	Read Length	Run Time
Flongle	Simultaneous sequencing of up to 126 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is up to ~ 2 Gb per run	1 min–16 hours
MinION	Simultaneous sequencing of up to 512 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is ~ 10 to 20 Gb, up to 42 Gb	1 min–72 hours
GridION	Simultaneous sequencing of up to 2,560 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is up to 210 Gb	1 min–72 hours
PromethION	Simultaneous sequencing of up to 128,400 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is up to 10,000 Gb (10 Tb)	1 min–72 hours
Plongle (in development)	Parallel sequencing with 96 flow cells	No limit to read length; highest to date is 4 million	1 min–72 hours

(RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT); RX3869 (Cote Expert Report) ¶ 293.)

Response to Finding No. 599

Complaint Counsel objects to the proposed finding because it misattributes the source of documents, improperly cites expert testimony, and is misleading.

Complaint Counsel objects to the attribution of RX3913, RX3543, RX3536, and RX3542—documents which Respondents purportedly captured from ONT's website—to ONT as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial

Findings at 3. Two of the documents (RX3913 and RX3543) contain content that is different than the content currently posted at the URL listed in these exhibits. These documents constitute hearsay. Given the inherent unreliable nature of these documents, they have little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support facts ([redacted]), in contravention of this Court's Order. This Court should disregard this evidence.

The proposed finding is vague because it does not make clear that the figures provided in the "Throughput" column refer to the number of fragments that can be sequenced simultaneously per run of the instrument, not per flow cell within each run.

The proposed finding is confusing and misleading because, underneath the "Read Length" column, it also provides the total output of each instrument run in bases (gigabases or terabases). The total output in bases of a sequencer per run of the instrument (or per period of time) is an irrelevant metric for the application of MCED tests. [redacted] Therefore, this Court should disregard the proposed finding.

600. Core components of ONT's long-read sequencing technology as well as other recent innovations have made its platform more suitable for multi-cancer screening. (*See* RX3869 (Cote Expert Report) ¶¶ 293, 295–98.)

Response to Finding No. 600

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony, Dr. Cote is not qualified to provide expert testimony on this subject, Dr. Cote's opinion is not reliable, Dr. Cote is not a credible witness, and it is against the weight of the evidence.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote to support the purported fact [redacted], in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED testing, because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). This Court should not accord Dr. Cote's opinion any weight.

In addition to Dr. Cote being unqualified, his opinions about which NGS platforms are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his

expertise; [redacted]. (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)).

[redacted]. (*See* CCFF ¶¶ 1346-69).

[redacted] (*See* CCFF ¶¶ 1370-98). Therefore, this Court should disregard the proposed finding.

> 600.1 Because it does not require PCR amplification, ONT's long-read sequencing eliminates amplification bias while preserving base modifications, making it ideal for epigenomic analysis such as methylation profiling. (RX3439 (Mantere et al., 2019) at 2; *see also* RX3236 (Folkard et al., Methylation with Oxford Nanopore Technologies Video Seminar).) ONT recently released a Cas9 targeted nanopore sequencing kit, which enables high depth sequencing and retains methylation patterns and other base modifications. (RX3537 (ONT).)

Response to Finding No. 600.1

Complaint Counsel objects to the proposed finding because it is misleading, improperly cites a third-party video that is not in evidence, and is vague.

The proposed finding is misleading to the extent that it suggests ONT long-read sequencing can be used for MCED testing. The Matere et al. paper (RX3439) discusses only applications that involve sequencing of genomic DNA templates for which long read lengths are an advantage; it contains no mention of MCED testing or any liquid biopsy application that involves sequencing cell-free DNA templates. Similarly, the description of the ONT Cas9 sequencing kit contained in RX3537 (which purports to be a printout from ONT's website)

simply says nothing whatsoever about MCED testing or any liquid biopsy application.

RX3236 is a one-page printout that purports to be printed from an ONT web page at which a video is posted. The video posted at the URL listed in this document has not been admitted into evidence, and therefore Respondents may not rely on it for evidentiary support. Moreover, Respondents provide no specific citation, substantive point, quotation, timestamp or other reference by which this Court could even locate any content in this video that purportedly This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). This citation does not comply with that order. This Court should disregard RX3236, as well as the video posted on an external website that is not in evidence.

The proposed finding is vague because it does not define "high depth sequencing." Therefore, this Court should disregard the proposed finding.

> 600.2 ONT's nanopore sequencing technology is capable of directly detecting methylation and other epigenomic markers on DNA or RNA, without the bisulfite conversion step used by other sequencing technologies (*e.g.*, for Illumina's sequencing technology) that can cause sample degradation, and that can complicate data analysis. (RX3869 (Cote Expert Report) ¶ 295.)

Response to Finding No. 600.2

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony and is misleading, Dr. Cote is not qualified to provide expert opinion testimony on this subject, Dr. Cote is not a credible witness, and Dr. Cote's opinion is not reliable.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote [redacted], in contravention of this Court's Order. This Court should disregard this evidence.

The proposed finding is misleading to the extent that it suggests ONT long-read sequencing can be used for MCED testing. The proposed finding is against the weight of significant evidence showing that extremely inefficient long-read NGS platforms such as ONT's platform are not a viable option for MCED testing. [redacted] (*See* CCFF ¶¶ 1346-69). [redacted] (*See* CCFF ¶¶ 1370-98).

Dr. Cote is not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED testing, because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). This Court should not accord Dr. Cote's opinion any weight.

In addition to Dr. Cote being unqualified, his opinions about which NGS platforms are viable for MCED testing is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; [redacted] (*See* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects)). Therefore, this Court should disregard the proposed finding.

600.3 Using ONT's nanopore sequencing, researchers have directly identified epigenomic modifications at nucleotide resolution, including DNA methylation, with detection of other epigenomic modifications possible through training base-calling algorithms. (RX3539 (ONT).)

Response to Finding No. 600.3

Complaint Counsel objects to the proposed finding because it misattributes the source of documents and is misleading.

Complaint Counsel objects to the attribution of RX3539—a document which Respondents purportedly captured from ONT's website—to ONT as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This document constitutes hearsay. Given the inherent unreliable nature of these documents, they have little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

The proposed finding is misleading to the extent that it suggests ONT long-read sequencing can be used for MCED testing. RX3539 does not discuss MCED testing or even liquid biopsy applications. The proposed finding is against the weight of significant evidence showing that extremely inefficient long-read NGS platforms such as ONT's platform are not a viable option for MCED testing. [redacted] (*See* CCFF ¶¶ 1346-69). [redacted]. (*See* CCFF ¶¶ 1370-98). Therefore, this Court should disregard the proposed finding.

600.4 The use of ONT's nanopore direct sequencing also means that DNA methylation and other base modifications data is captured together with sequence data and is available for analysis at any future timepoint. (RX3539 (ONT).)

Response to Finding No. 600.4

Complaint Counsel objects to the proposed finding because it misattributes the source of documents and is misleading.

Complaint Counsel objects to the attribution of RX3539—a document which Respondents purportedly captured from ONT's website—to ONT as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This document constitutes hearsay. Given the inherent unreliable nature of these documents, they have little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

The proposed finding is misleading to the extent that it suggests ONT long-read sequencing can be used for MCED testing. RX3539 does not discuss MCED testing or even liquid biopsy applications. The proposed finding is against the weight of significant evidence showing that extremely inefficient long-read NGS platforms such as ONT's platform are not a viable option for MCED testing. [redacted]. (*See* CCFF ¶¶ 1346-69). [redacted] (*See* CCFF ¶¶ 1370-98). Therefore, this Court should disregard the proposed finding.

> 600.5 ONT's MinION nanopore sequencer has also been used by researchers for ChIP-Seq to study protein-DNA binding activity and strength. (*See* RX3077 (Borlin et al., 2020).) Researchers are also improving the Rapid Analysis of ChIP-Seq data (RACS) software for the analysis of ONT's nanopore sequencing data. (*See* RX3620 (Saettone et al., 2019).)

Response to Finding No. 600.5

Complaint Counsel objects to the proposed finding because it is misleading to the extent that it suggests ONT long-read sequencing can be used for MCED testing. RX3077 and RX3620 do not discuss MCED testing or even liquid biopsy applications. The proposed finding is against

the weight of significant evidence showing that extremely inefficient long-read NGS platforms such as ONT's platform are not a viable option for MCED testing. [redacted]. (*See* CCFF ¶¶ 1346-69). [redacted] (*See* CCFF ¶¶ 1370-98). Therefore, this Court should disregard the proposed finding.

601. While ONT has historically focused on long-read sequencing, recently published research has demonstrated ONT's capability to perform short-read sequencing. (PFF ¶¶ 601.1–601.4.) Such research suggests that ONT's nanopore sequencers are "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time". (RX3446 (Martignano et al., 2021) at 1.)

Response to Finding No. 601

Complaint Counsel objects to the proposed finding because it is misleading, unsupported, and against the weight of the evidence.

The proposed finding is misleading because it is taken, verbatim, from Dr. Cote's report (RX3869 (Cote Report) ¶ 297) but is not attributed to him. This is no doubt because Dr. Cote made the highly misleading and unsupported claim during trial that, using the technique of ligating short DNA template molecules together into a longer molecule, "instead of many millions of reads that need to be done, only one read needs to be done in the case of the ONT platform." (Cote Tr. 3755). However, none of the Martignano et al. paper (RX3446) cited in RPFF ¶ 601 and 601.4, the Wei et al. paper (RX3737) cited in RPFF ¶ 601.1, the Wilson et al. paper (RX3744) cited in RPFF ¶ 601.2, or the Marcozzi et al. paper (RX3441) cited in RPFF ¶ 601.3, below, demonstrated or made any claim of concatenating anything approaching "millions" of short molecules together, even as a one-time proof of concept experiment (never mind an actual robust and reliable protocol that could meet the extreme performance demands of clinical MCED testing). Moreover, Respondents did not obtain any documents or testimony from ONT or the study authors. These articles constitute out-of-court statements being offered for the truth

of the matter asserted and thus constitute unreliable hearsay evidence. As such, the Court ought not give this evidence any weight.

[redacted]

[redacted]

The proposed finding is also misleading because it claims that the Martignano et al. paper cited (RX3446) was "recently published," when in fact it was published back in February 2021, well before discovery and trial in this matter. The other papers cited in RPFF ¶¶ 601.4-601.4 were published as far back as 2016 (*see* RX3737, Wei et al, 2016). But Respondents' counsel did not ask any MCED witness a single question about any of these papers that supposedly hold the key to making long-read sequencing platforms viable for MCED testing.

The proposed finding is against the weight of significant evidence showing that extremely inefficient long-read NGS platforms such as ONT's platform are not a viable option for MCED testing[redacted]. (*See* CCFF ¶¶ 1346-69).

[redacted]. (*See* CCFF ¶¶ 1370-98). Therefore, this Court should disregard the proposed finding.

> 601.1 For example, in 2016, researchers from the Albert Einstein College of Medicine developed a method that enabled rapid real-time sequencing of short DNA fragments using the MinION nanopore sequencer in a test for aneuploidy. (RX3737 (Wei & Williams 2016).)

Response to Finding No. 601.1

Complaint Counsel objects to the proposed finding because it is misleading, unsupported, and against the weight of the evidence. Complaint Counsel's response to proposed sub-findings 601.1-601.4 is set forth in response to proposed finding 601, above. (*See* Response to RPFF ¶

601, above). Therefore, this Court should disregard the proposed finding.

601.2 In 2019, researchers from the Stanford University developed a rolling-circle amplification method to produce long stretches of concatemeric repeats of short DNA sequences <100 bp from cfDNA that is sensitive enough to achieve SNV (single-nucleotide variants) discrimination in mixtures of sequences and enables quantitative detection of specific variants present at ratios of <10% using ONT's MinION nanopore sequencer. (RX3744 (Wilson et al., 2019).)

Response to Finding No. 601.2

Complaint Counsel objects to the proposed finding because it is misleading, unsupported, and against the weight of the evidence. Complaint Counsel's response to proposed sub-findings 601.1-601.4 is set forth in response to proposed finding 601, above. (*See* Response to RPFF ¶ 601, above). Therefore, this Court should disregard the proposed finding.

601.3 In 2020, researchers from Utrecht University of the Netherlands developed a CyclomicsSeq method that uses similar rolling-circle amplification to accurately detect lowly abundant (0.02%) circulating tumor DNA (ctDNA) from liquid biopsies of patients with head-and-neck squamous cell carcinoma (HNSCC) using MinION nanopore sequencer. (RX3441 (Marcozzi A et al., 2020).)

Response to Finding No. 601.3

Complaint Counsel objects to the proposed finding because it is misleading, unsupported, and against the weight of the evidence. Complaint Counsel's response to proposed sub-findings 601.1-601.4 is set forth in response to proposed finding 601, above. (*See* Response to RPFF ¶ 601, above). Therefore, this Court should disregard the proposed finding.

601.4 In February 2021, researchers from Italy also showed successful use of low-coverage MinION nanopore sequencing for profiling of copy number variation from plasma cfDNA from liquid biopsies of lung cancer patients as a reliable alternative to Illumina sequencing. (RX3446 (Martignano et al., 2021).)

Response to Finding No. 601.4

Complaint Counsel objects to the proposed finding because it is misleading, unsupported, and against the weight of the evidence. Complaint Counsel's response to proposed sub-findings

601.1-601.4 is set forth in response to proposed finding 601, above. (*See* Response to RPFF ¶ 601, above). Therefore, this Court should disregard the proposed finding.

602. ONT has also announced its intent to support the liquid biopsy market. (RX3470 (Nanopore); RX3521 (NCM) at 50–52; RX3167 (Nanopore); RX3520 (NCM) at 6, 9–10).)

Response to Finding No. 602

Complaint Counsel objects to the proposed finding because it misattributes the source of documents and is vague, misleading, and unsupported.

Complaint Counsel objects to the attribution of RX3470, RX3521, RX3167, and RX3520 to ONT as the source of the documents, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Two of the documents (RX3470 and RX3167) appear to be captures of pages on ONT's website where video is posted. Two of the documents (RX3521 and RX3520) appear to be transcriptions of the videos that Respondents purportedly had created. These documents constitute hearsay and are not reliable. ONT did not testify to explain their meaning or be tested on any statements contained within. Given the inherent unreliable nature of these documents, they have little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

The proposed finding is vague because it does not explain what is meant by "support" or what is meant by "liquid biopsy," which encompasses research and clinical applications far beyond MCED testing.

The proposed finding is unsupported because the sources cited do not evidence that ONT ever expressed "intent to support the liquid biopsy market."

The proposed finding is misleading to the extent it suggests ONT long-read sequencing

can be used for MCED testing. The cited documents do not discuss MCED testing. The proposed finding is against the weight of significant evidence showing that extremely inefficient long-read NGS platforms such as ONT's platform are not a viable option for MCED testing. [redacted]. (*See* CCFF ¶¶ 1346-69). [redacted] (*See* CCFF ¶¶ 1370-98). Therefore, this Court should disregard the proposed finding.

603. The per gigabase sequencing costs for ONT's NGS sequencers are comparable to those for the highest throughout Illumina NGS sequencers. (PFF ¶¶ 603.1–603.3.)

Response to Finding No. 603

Complaint Counsel objects to the proposed finding because it is misleading in that it employs the metric of cost per gigabase, which is irrelevant when utilizing NGS for liquid biopsy applications such as MCED testing. For liquid biopsy applications, the cost per patient sample is driven by the cost per read (i.e., per fragment), not the cost per base. [redacted]

[redacted]

603.1 For example, the University of Wisconsin-Madison Biotechnology Center offers ONT nanopore sequencing at $730 for a single cell, $1250 for GridION and $2100 for a PromethION run. (RX3717, University of Wisconsin-Madison Biotechnology Center.)

Response to Finding No. 603.1

Complaint Counsel objects to the proposed finding because it is confusing, misleading, and based on unreliable hearsay.

The proposed finding is confusing because the previous proposed finding discussed "per gigabase" pricing, and now this proposed sub-finding purports to provide an "example," yet the example is about pricing per flow cell or per run, not per gigabase.

The proposed finding is misleading in that it employs the metric of cost per gigabase, which is irrelevant when utilizing NGS for liquid biopsy applications such as MCED testing. For liquid biopsy applications, the cost per patient sample is driven by the cost per read (i.e., per fragment), not the cost per base. [redacted] In contrast, none of Respondents' witnesses, including purported multi-subject expert Dr. Cote, explained how

sequencing cost "per gigabase" is relevant to MCED testing, nor walked this Court through any calculation of sequencing cost for Grail's test or any other test to illustrate how cost per gigabase is a supposedly useful metric to MCED testing.

RX3539 appears to be a document that Respondents purportedly captured from a third-party website. This document constitutes hearsay. Given its inherent unreliable nature, it has little to no probative value. (*See* Rule 4.43(b)). Respondents elected not to pursue any form of discovery from sequencing labs purportedly offering ONT sequencing, likely because they know such evidence would not support their contention that anyone in the real world is using ONT for MCED test development or any other clinical liquid biopsy application. Therefore, this Court should disregard the proposed finding.

> 603.2 A PromethION customer reported repeatedly achieving 220 Gb of sequencing data output per single $625 flow cell, making per Gb cost for the PromethION only $3/Gb. (RX3698 (Amadeus Capital).)

Response to Finding No. 603.2

Complaint Counsel objects to the proposed finding because it relies on double hearsay and is misleading.

RX3698 appears to be a story that Respondents purportedly captured from the website of a company named Amadeus Capital that did not appear in this matter. The story states that "a PromethION customer reported" achieving 220 Gb of data. This constitutes double hearsay. Given its inherent unreliable nature, it has little to no probative value. (*See* Rule 4.43(b)). This Court should disregard this evidence.

The proposed finding is misleading in that it employs the metric of cost per gigabase, which is irrelevant when utilizing NGS for liquid biopsy applications such as MCED testing. For liquid biopsy applications, the cost per patient sample is driven by the cost per read (i.e., per fragment), not the cost per base. [redacted]

[redacted] In contrast, none of Respondents' witnesses, including purported multi-subject expert Dr. Cote, explained how sequencing cost "per gigabase" is relevant to MCED testing, nor walked this Court through any calculation of sequencing cost for Grail's test or any other test to illustrate how cost per gigabase is a supposedly useful metric to MCED testing. Therefore, this Court should disregard the proposed finding.

> 603.3 ONT states that its PromethION can achieve best in field yield per flow cell of 254 Gb at $625 flow cell, making best per Gb cost for the PromethION only $2.55. (RX3543 (ONT) (showing $625 per flow cell at 245 Gb).)

Response to Finding No. 603.3

Complaint Counsel objects to the attribution of RX3543—a document which Respondents purportedly captured from ONT's website—to ONT as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

The proposed finding is vague because it does not explain what is meant by "best in field."

The proposed finding is misleading in that it employs the metric of cost per gigabase, which is irrelevant when utilizing NGS for liquid biopsy applications such as MCED testing. For liquid biopsy applications, the cost per patient sample is driven by the cost per read (i.e., per fragment), not the cost per base. [redacted] In contrast, none of Respondents' witnesses, including purported multi-subject expert Dr. Cote, explained how sequencing cost "per gigabase" is relevant to MCED testing, nor walked this Court through any calculation of sequencing cost for Grail's test or any other test to illustrate how cost per gigabase is a supposedly useful metric to MCED testing. Therefore, this Court should disregard the proposed finding.

604. With regard to accuracy, ONT has announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1.)

Response to Finding No. 604

Complaint Counsel objects to the proposed finding because it misattributes the source of documents and is vague and misleading.

Complaint Counsel objects to the attribution of RX3541 and RX3535—documents which

Respondents purportedly captured from ONT's website—to ONT as the source of the documents, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

The proposed finding is vague because it does not specify what percentage of bases ONT even claims will score above Q20 accuracy. Providing a Q score without specifying the percentage of bases sequenced that achieve that Q score is a meaningless statistic. For example, "Illumina NGS sequencers are about 99.9% accurate (>87% of bases >Q30) in calling the correct base from the DNA sequence" (*see* RPFF 576, above), placing Illumina's accuracy far above ONT's.

The proposed finding is misleading to the extent it suggests that ONT's accuracy level is sufficient for MCED testing. [redacted] (*See* CCFF ¶¶ 1370-98). For example, [redacted] Therefore, this Court should disregard the proposed finding.

> 604.1 In addition, methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).)

Response to Finding No. 604.1

Complaint Counsel objects to the proposed finding because it misattributes the source of documents and is vague, unsupported, confusing, and misleading.

Complaint Counsel objects to the attribution of RX3541, RX3535, and RX3536—

documents which Respondents purportedly captured from ONT's website—to ONT as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents elected not to pursue any form of discovery from ONT in this action, likely because they know such evidence would not support their contention that ONT is a feasible alternative NGS platform available for MCED developers.

The proposed finding is vague because it does not explain what is meant by "methods … to obtain consensus sequences from homogenous DNA samples by genome assembly."

The proposed finding is unsupported because none of the sources cited discuss "homogenous DNA samples" or "accuracies of more than 99.999% (Q50)" or any similar concept.

The proposed finding is confusing because it does not even purport to have anything whatsoever to do with MCED testing.

The proposed finding is also misleading to the extent it suggests that ONT's accuracy level is sufficient for MCED testing. [redacted]. (*See* CCFF ¶¶ 1370-98). For example, [redacted] Therefore, this Court should disregard the proposed finding.

B. New and Future Entrants

1. Singular Genomics

605. Singular Genomics was founded in 2016 and is headquartered in La Jolla, California. (PX8561 (Singular) at 15.) Singular has developed a sequencing-by-synthesis NGS platform comprising their NGS instrument, called the G4 Instrument, and associated consumable

kits, which they refer to collectively as the G4 Integrated Solution or the G4 System. (PX8561 (Singular) at 1–2.)

Response to Finding No. 605

[redacted]

[redacted]

606. Singular has also developed multiomics platform that incorporates NGS called the PX System. (PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 17).) Singular has completed pilot testing of its G4 System, involving their first external third-party evaluation, and is about to launch its early-access program. (PX7117 (Velarde (Singular) Dep. at 22–23).)

Response to Finding No. 606

[redacted]

[redacted] Singular warned its investors that "our limited operating history makes it difficult to evaluate our future prospects." (PX0068 at 023 (Singular Genomics S-1, May 2021)).

[redacted] If it cannot obtain additional funding, Singular warned investors that it may be required "to delay, scale back, or cease our product development or commercialization activities." (PX0068 at 035 (Singular Genomics S-1, May 2021)). Lastly, Singular expects to face "future litigation by third parties, including our competitors, who have patent and other intellectual property rights and may allege that our research and development activities, products, manufacturing methods, software and/or technologies infringe, misappropriate or otherwise violate their intellectual property rights." (PX0068 at 046 (Singular Genomics S-1, May 2021)**;** *see also* [redacted]

[redacted]

607. Singular commercially launched the the G4 NGS sequencer at the end of 2021 and will begin shipping the G4 NGS systems in the first half of 2022. (Velarde (Singular) Tr. 4515–16, 4522; *see also* PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31).)

Response to Finding No. 607

Complaint Counsel objects to this proposed finding as confusing and misleading.

This proposed finding is confusing because it uses the term "commercially launched" to mean something other than "commercially launched." [redacted] At trial when Singular's Velarde was asked "[d]oes Singular have any products in development currently?" Velarde answered "Yes, we do. . . We have what we are referring to as the G4 sequencer and a PX system as well." (Velarde, Tr. 4513). Likewise, Velarde testified, "Yeah, so the G4 hasn't been launched, and we probably won't do that until the end of next year." (Velarde, Tr. 4531).

This proposed finding is misleading, as it implies that Singular Genomics' expectation that it will begin shipping units in the second quarter of 2022 signifies that it will achieve meaningful commercial sales in the near future. [redacted]

[redacted]

608. Singular's mission is to develop fast, powerful, efficient, flexible sequencing platforms to solve challenges, such as long analysis times, labor intensive protocols, sample batching requirements and high cost, that sequencing technologies face in oncology, including for early cancer detection. (PX8561 (Singular) at 92.)

Response to Finding No. 608

Complaint Counsel objects to this proposed finding, as it is misleading and misrepresents the document which Respondents cite. Singular's Form S-1 states that "Our mission is to accelerate genomics for the advancement of science and medicine." (PX8561 (Singular) at 095). At no point does Singular ever state that its mission is to develop sequencing platforms for early cancer detection. (PX8561 (Singular) at 095-96). Rather, Singular states that it is "focused on oncology where there is an increasing need for higher sensitivity technology such as rare variant detection in liquid biopsy." (PX8561 (Singular) at 095). [redacted]

Complaint Counsel further objects to the extent that Respondents claim that MCED test developers consider "sample batching requirements" to be a challenge, as not a single document from, nor any testimony by an MCED test developer supports that proposition. (*See generally* CCFF ¶¶ 886-1500). For the reasons stated, this Court should disregard the proposed finding.

609. The G4 System's performance characteristics claim to be comparable or better to Illumina's NextSeq and NovaSeq systems:

Response to Finding No. 609

Complaint Counsel object to the proposed finding because it is unsupported, as it does not cite to any evidence of record. Therefore, this Court should disregard the proposed finding.

609.1 Throughput of greater than 100 million paired-end reads per flow cell for four flow cells; targeted 330 million reads per flow cell at commercial launch for a total of 1,320 million reads. (Velarde (Singular) Tr. 4528–30; PX8561 (Singular) at 4–5; [redacted]

Response to Finding No. 609.1

[redacted]

[redacted]

[redacted]

609.2 Read lengths of 50 bases to 150 bases. (PX8561 (Singular) at 4–5; [redacted]

Response to Finding No. 609.2

[redacted]

[redacted]

609.3 Targeted 400 Gbs per sequencing run. (PX8561 (Singular) at 4–5; [redacted]

Response to Finding No. 609.3

[redacted]

[redacted]

[redacted]

[redacted]

609.4 High speed sequencing at 4.0 minute cycle time, with a targeted 2.5 minute cycle time that will generate a sequencing time of approximately 16 hours to complete a 2x150 base run. (PX8561 (Singular) at 4–5; [redacted]

Response to Finding No. 609.4

[redacted]

[redacted]

[redacted]

609.5 High accuracy of 99.7% on 150 base reads (>70% Q30 on base calls, with targeted >80% Q30 on base calls at launch); 99.99% (Q40) accuracy with the "HD-Seq" methodology. (PX8561 (Singular) at 4–5; PX7117 [redacted]

Response to Finding No. 609.5

[redacted]

[redacted]

609.6 Independent, flexible throughput that uses flow cells with independent lanes, enabling libraries to be kept separate in each lane while still retaining high throughput capacity. (PX8561 (Singular) at 4–5; [redacted]

Response to Finding No. 609.6

[redacted]

[redacted]

610. Singular expects that the G4 System will compete with Illumina for sales of sequencers and integrated systems to multicancer early detection test developers. [redacted] Tr. 4522, [redacted] *see also* PX8561 (Singular) at 8.)

Response to Finding No. 610

[redacted]

[redacted]

[redacted]

611. Singular is targeting clinical oncology applications for the G4 system; Singular is developing HD-Seq as one of the potential applications for MCED tests; Singular believes that in addition to faster turnaround time in clinical settings, Singular's HD sequencing process also

gives it an advantage; Singular expect to compete with Illumina for sales of sequencers and consumables to MCED test developers. (Velarde (Singular) Tr. 4522, [redacted]

Response to Finding No. 611

[redacted]

[redacted]

612.

Response to Finding No. 612

[redacted]

[redacted]

613. Singular does not believe that Illumina's reacquisition of GRAIL will have an effect on Singular's ability to innovate in the NGS space and Singular does not project that Illumina's reacquisition of GRAIL will slow down Singular's commercialization plans. (Velarde (Singular) Tr. 4534.)

Response to Finding No. 613

[redacted]

2. **Ultima Genomics**

614. Ultima Genomics, a biotechnology company based in Newark, California, is developing a low-cost alternative sequencing-by-synthesis platform to Illumina's highest throughput instrument and flow cell (NovaSeq 6000 with S4 flow cells) aimed at high-volume users. (PX7119 (Lauer (Ultima) Dep. at 34–36, 146–48).)

Response to Finding No. 614

Complaint Counsel objects to this proposed finding as vague and misleading.

[redacted]

[redacted]

615. [redacted]

Response to Finding No. 615

[redacted]

[redacted]

[redacted]

616. [redacted]

Response to Finding No. 616

[redacted]

617. [redacted]

Response to Finding No. 617

[redacted]

[redacted]

617.1 [redacted]

Response to Finding No. 617.1

[redacted]

[redacted]

617.2 [redacted]

Response to Finding No. 617.2

[redacted]

[redacted]

[redacted]

618. [redacted]

Response to Finding No. 618

[redacted]

[redacted]

619. [redacted]

Response to Finding No. 619

[redacted]

[redacted]

620. [redacted]

Response to Finding No. 620

[redacted]

[redacted]

[redacted]

621. [redacted]

Response to Finding No. 621

[redacted]

[redacted]

622. [redacted]

Response to Finding No. 622

[redacted]

[redacted]

[redacted]

622.1 [redacted]

Response to Finding No. 622.1

[redacted]

[redacted]

622.2 [redacted]

Response to Finding No. 622.2

[redacted]

[redacted]

[redacted]

623. [redacted]

Response to Finding No. 623

[redacted]

[redacted]

[redacted]

3. **Roche**

624. Roche Diagnostics, parent of the company that previously brought to the market the first NGS sequencer—the 454 GS FLX Titanium sequencer—in 2005, acquired two NGS sequencer developers: Stratos Genomics that is developing a nanopore DNA sequencing technology utilizing Sequencing by Expansion (SBX), and Genia Technologies that is developing a single-molecule, nanopore technology. (RX3407 (Kircher et al., 2010); RX3615 (Roche); RX3614 (Roche).)

Response to Finding No. 624

Complaint Counsel objects that the proposed finding is not supported by the evidence that Respondents cite, misattributes the source of documents, and should be disregarded.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 310), even though Respondents do not attribute it to Dr. Cote, and represents his opinion rather than market realities.

None of the documents that Respondents do cite makes any reference to a planned Roche sequencer, Stratos Genomics, or Genia Technologies. RX3407 (Kircher et al., 2010) is an academic paper from 2010 that discusses four then-contemporary sequencing instruments. It does not have any information about any planned Roche sequencing instrument. RX3614 appears to be a page Respondents captured from Roche's website announcing a partnership between Roche and Illumina, under which Illumina would grant Roche rights to develop and distribute in vitro diagnostic (IVD) tests on Illumina's NGS platform, although the document was not produced by Roche. Nothing in the document makes any mention of a planned Roche sequencing instrument; on the contrary, the only sequencing instrument mentioned in the document is Illumina's NextSeq550Dx. RX3615 appears to be another page Respondents captured from Roche's website describing a research-use only kit for analyzing tumor DNA from a tissue sample. Nothing in the document makes any mention of a planned Roche sequencing instrument; on the contrary, the only sequencing instrument mentioned in the document is Illumina's NextSeq 500. Because this finding is not supported by any of the documents that Respondents cite, this Court should disregard this finding.

625. Roche expects to bring to market an NGS nanopore sequencer by the 2024 time frame. (RX3614 (Roche).)

Response to Finding No. 625

Complaint Counsel objects to this proposed finding as misleading and unsupported.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 310), even though Respondents do not attribute it to Dr. Cote, and represents his opinion rather than market realities. Respondents omit an important qualification from Dr. Cote's report: [redacted] Dr. Cote's musings on "the evidence" based on the limited evidence he personally reviewed are irrelevant and represent unreliable and improper expert opinion.

Respondents now attempt to substitute a new purported source for Dr. Cote's unsupported claim: RX3614, which Respondents appear to have printed from the Internet (Roche did not produce the document), and which has nothing to do with any nanopore sequencer. Because the cited source fails to support this proposed "finding" (penned by Dr. Cote), this Court should reject it.

626. [redacted]

Response to Finding No. 626

[redacted]

[redacted]

627.

Response to Finding No. 627

[redacted]

628. [redacted]

Response to Finding No. 628

[redacted]

[redacted]

628.1 [redacted]

Response to Finding No. 628.1

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

629. [redacted]

Response to Finding No. 629

[redacted]

[redacted]

[redacted]

630. [redacted]

Response to Finding No. 630

[redacted]

631.

Response to Finding No. 631

[redacted]

4. **Element**

632. Element Biosciences is a biotechnology company headquartered in San Diego, California that was founded in 2017. [redacted] Element is developing a currently unnamed NGS platform through its sequencing-by-trapping technology. (RX3186 (Element Biosciences, International Patent Application No. WO2020242901).) [redacted]

Response to Finding No. 632

[redacted]

[redacted]

633. Element's focus for its platform is to provide high-quality, low cost, easy-to-use DNA sequencing tools in order to increase accessibility of sequencing to individual labs. [redacted]

Response to Finding No. 633

[redacted]

[redacted]

634. [redacted]

Response to Finding No. 634

[redacted]

[redacted]

[redacted]

635. [redacted]

Response to Finding No. 635

[redacted]

[redacted]

636. [redacted]

Response to Finding No. 636

[redacted]

[redacted]

637. [redacted]

Response to Finding No. 637

[redacted]

[redacted]

[redacted]

638. [redacted]

Response to Finding No. 638

[redacted]

[redacted]

[redacted]

5. **Omniome**

639. Omniome is a biotechnology company headquartered in San Diego, California that was founded in 2013. (PX7071 (Song, IHT at 13).) In July 2021, Pacific Biosciences of California ("PacBio") announced it had acquired Omniome for $800M. (RX3947 (Clinical OMICs).)

Response to Finding No. 639

Complaint Counsel objects to the attribution of RX3947 to Clinical OMICs, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents did not take discovery from any entity named "Clinical OMICs," and no entity by the name of "Clinical OMICs" produced any documents in this matter. RX3947 appears to be a document that Respondents purportedly captured from a third-party website. This document constitutes hearsay. Given its inherent unreliable nature, it has little to no probative value. (*See* Rule 4.43(b)). Complaint Counsel has no other specific response to the proposed finding.

639.1 Many of PacBio/Omniome's senior executives came from Illumina: PacBio CEO Christian Henry held several positions at Illumina, including former Chief Commercial Officer; Omniome President Richard Shen is a former Illumina Vice President of Oncology R&D. (RX3947 (Clinical OMICs) at 2.)

Response to Finding No. 639.1

Complaint Counsel objects to the attribution of RX3947 to Clinical OMICs, in

contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents did not take discovery from any entity named "Clinical OMICs," and no entity by the name of "Clinical OMICs" produced any documents in this matter. RX3947 appears to be a document that Respondents purportedly captured from a third-party website. This document constitutes hearsay. Given its inherent unreliable nature, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is unsupported because it makes a claim regarding "many" executes but provides only two examples.

The proposed finding is misleading to the extent it suggests that merely by virtue of employing former Illumina executives, Omniome constitutes a competitor to Illumina or a feasible alternative NGS platform for MCED testing. For the reasons stated, this Court should disregard the proposed finding.

640. The combined PacBio and Omniome have said they would specifically target the cancer screening market, as well as other oncology applications. (RX3947 (Clinical OMICs) at 3.)

Response to Finding No. 640

Complaint Counsel objects to the attribution of RX3947 to Clinical OMICs, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents did not take discovery from any entity named "Clinical OMICs," and no entity by the name of "Clinical OMICs" produced any documents in this matter. RX3947 appears to be a document that Respondents purportedly captured from a third-party website. This document constitutes hearsay. Given its inherent unreliable nature, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading and against the weight of the evidence to the extent it suggests that any planned Omniome sequencer is a viable platform for MCED testing. The

proposed finding is against the weight of the evidence from [redacted]

[redacted]

640.1 PacBio stated that it believes Omniome's data accuracy should help the combined company target oncology applications like cancer screening. RX3947 (Clinical OMICs) at 3.)

Response to Finding No. 640.1

Complaint Counsel objects to the attribution of RX3947 to Clinical OMICs, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents did not take discovery from any entity named "Clinical OMICs," and no entity by the name of "Clinical OMICs" produced any documents in this matter. RX3947 appears to be a document that Respondents purportedly captured from a third-party website. The author of this document claims to report what PacBio CEO Christian Henry purportedly said during an interview for which the author was not present. As such, this evidence constitutes double hearsay and has no probative value. (*See* Rule 4.43(b)). Moreover, the document does not even directly quote Mr. Henry, making it vague and misleading.

The proposed finding is misleading and against the weight of the evidence to the extent it suggests that any planned Omniome sequencer is a viable platform for MCED testing. The proposed finding is against the weight of the evidence from [redacted]

[redacted]

641. Omniome is developing an NGS sequencer using its sequencing-by-binding technology. (RX3533 (Omniome).)

Response to Finding No. 641

[redacted]

642. Omniome's sequencer will reportedly have comparable throughput and run times to Illumina's NexSeq sequencers, but with better accuracy—98%> Q50 to 99% Q70—10 to 100x better than the accuracy of Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted]

Response to Finding No. 642

[redacted]

[redacted]

642.1 Omniome expects that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted]

Response to Finding No. 642.1

[redacted]

[redacted]

[redacted]

642.2 In a recent earnings call, PacBio CEO Christian Henry claimed that PacBio/Omniome's "error rates are so low, we're more than 15-fold better than what other SBS players can do today". (RX4050 (PacBio) at 7.)

Response to Finding No. 642.2

Complaint Counsel objects to this proposed finding because it misattributes the source of documents, relies on hearsay evidence, is unreliable, and misleading.

Complaint Counsel objects to the attribution of RX4050, a document that appears to have been downloaded from a third-party website, to PacBio as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Respondents elected

not to pursue any form of discovery from PacBio in this action, likely because they know such evidence would not support their contention that PacBio's subsidiary Omniome will be a feasible alternative NGS platform available to MCED developers in the United States any time in the foreseeable future.

Complaint Counsel further objects to RX4050, which appears to be a document that Respondents purportedly captured from a third-party website, as hearsay. Given its inherent unreliable nature, it has little to no probative value. (*See* Rule 4.43(b)).

Complaint Counsel further objects to the proposed finding because it is unreliable, as it consists of biased, unproven puffery, and lacks critical context such as cost and throughput specifications. The purported quote also does not explain whether the error rates being described are random or systematic, [redacted] Respondents seek to use this out of context hearsay to support their baseless contention, even though the very text that they quote makes no mention of MCED testing, or even liquid biopsy. The Court should assign no weight to this hearsay. For the reasons stated, this Court should disregard the proposed finding.

643. [redacted]; RX3189 (Encodia).) Omniome currently plans to launch its sequencer in early 2023. (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

Response to Finding No. 643

[redacted]

[redacted]

[redacted]

644. Omniome expects its NGS platform will be used for "applications like cancer," and has general interest in oncology, including companies that are developing blood-based early cancer screening tests. (PX7096 (Song (Omniome) Dep. at 59–63, 66); [redacted]

Response to Finding No. 644

[redacted]

[redacted]

C. Switching Platforms

645. Switching between Illumina's platform and alternative platforms is feasible. (RX3869 (Cote Expert Report) ¶ 336.) To the extent a test developer believes this sort of switching is costly, there are alternative methods of switching between platforms, including concurrent development on multiple platforms. (RX3869 (Cote Expert Report) ¶ 336.)

Response to Finding No. 645

Complaint Counsel objects to the proposed finding because it is unsupported, vague, conclusory, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

[redacted]

The proposed finding is conclusory because it cites no support other than Dr. Cote who merely declares this sweeping generalization to be true.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—a portion of it is merely copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted]

[redacted]

Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on the subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on the subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and

does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

646. In fact, cancer screening developers will inevitably need to switch between different Illumina instruments in the course of developing their respective screening tests. (RX3869 (Cote Expert Report) ¶ 336.)

Response to Finding No. 646

Complaint Counsel objects to the proposed finding because it cites only unreliable self-serving testimony, it is misleading and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

[redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted]

[redacted]

Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on the subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not

accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

646.1 Illumina's own model contemplates that a portion of test developers will switch to an alternative sequencing platform developer in the process of upgrading Illumina instruments. (PX7087 (Goswami (Illumina) Dep. at 16).)

Response to Finding No. 646.1

Complaint Counsel objects to the proposed finding because it is unsupported and vague.

The proposed finding is unsupported because the source cited (PX7087 (Goswami (Illumina) Dep. at 16) does not state or even relate to the purported fact.

The proposed finding is vague because it does not explain or define "Illumina's own model." Therefore, this Court should disregard the proposed finding.

1. **Feasibility**

647. Test developers routinely re-validate their tests to account for new developments in their tests, new and improved technology relating to consumables or sequencers, or for any number of other reasons. (RX3869 (Cote Expert Report) ¶ 338.) These revalidations are part of a good test developer's business plan. (RX3869 (Cote Expert Report) ¶ 338.) It is routine to switch or to upgrade platforms (which from a re-validation point of view is equivalent). (Cote Tr. 3739; Aravanis (Illumina) Tr. 1865; (RX3869 (Cote Expert Report) ¶ 338.) This is built into all clinical labs' workflow and plan for long-term functioning for the lab. (Cote Tr. 3771.)

Response to Finding No. 647

Complaint Counsel objects to the proposed finding because it is misleading, vague, speculative, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading because it implies that re-validating a test on an existing platform after a small change to one component is anywhere near equivalent to switching a test from an Illumina NGS platform to a purported alternative NGS platform.

[redacted]

[redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted nearly verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted] Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

648. Given that test developers will need to undergo such redevelopment simply to maintain their use of Illumina's instruments, there are multiple opportunities for test developers to switch to alternative sequencing platforms, or validate an alternative sequencing platforms for the purposes of managing their supply chain. (RX3869 (Cote Expert Report) ¶ 338.)

Response to Finding No. 648

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79).

Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

649. For companies developing early cancer screening tests, these requirements for such switching to a different NGS platform or another cancer screening modality are no different from the requirements to modify their tests to use different biomarkers, different reagents, or different testing equipment, for versioning, costs, or whatever the reason, either during or after

the initial development of the tests, which happens rather frequently. (RX3869 (Cote Expert Report) ¶ 339; Cote Tr. 3786–87.)

Response to Finding No. 649

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, and it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it is unclear what "such switching" refers to, it does not explain what the "another cancer screening modality" or "modify their tests" means, it does not identify any purported "different NGS platform," and it does not define "versioning." The proposed finding is also vague in its use of "whatever the reason." It is also not clear what is meant by "rather frequently."

The proposed finding is misleading because it implies that making any type of ill-defined midification to a test on an existing platform is anywhere near equivalent to switching a test from an Illumina NGS platform to a purported alternative NGS platform.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it merely copies and pastes an entire paragraph from Dr. Cote's report verbatim and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See generally* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted]

[redacted] Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed

finding.

650. [redacted] RX3419 (Lennon et al., 2020) at 18; RX3772 (Cohen 2018 Supplementary Material) at 2–3.) [redacted]

Response to Finding No. 650

[redacted]

[redacted]

650.1 [redacted]

Response to Finding No. 650.1

[redacted]

[redacted]

651. Similarly, FMI is using Illumina's HiSeq 2500 and 4000 as its NGS platforms for the FoundationOne CDx test for tissue biopsy sample based therapy selection, but switched to Illumina's NovaSeq 6000 for its FoundationOne® Liquid CDx test for liquid biopsy sample based therapy selection. (RX3231 (FMI) at 4; RX3234 (FMI) at 7.) There is no indication that

switching from HiSeq to NovaSeq meaningfully delayed FMI's development of the FoundationOne® Liquid CDx test, or its FDA approval, and neither Roche nor FMI have stated publicly that FMI faced delays from such switching. (RX3869 (Cote Expert Report) ¶ 341.)

Response to Finding No. 651

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to provide expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is unreliable.

The proposed finding is misleading because it attempts to portray the purported fact that FMI developed one test (FoundationOne CDx tissue biopsy test) on the Illumina HiSeq platform and then later developed a *different* test (FoundationOne Liquid CDx liquid biopsy test) on the Illumina NovaSeq platform as an example of switching an existing test from one platform to another. It is not an example of switching; they are two different tests.

[redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding FMI's test development. This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

652. Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." (PX7111 (Fesko (Natera) Dep. at 251–52); RX3062 (BGI) at 1.) Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform. (RX3499 (Natera) at 6.)

Response to Finding No. 652

Complaint Counsel objects to the proposed finding because it misattributes the source of

a document, it cites unreliable hearsay, it is vague, misleading, unsupported, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

Complaint Counsel objects to the attribution of RX3062 to BGI as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. RX3062 appears to be a document Respondents purportedly captured from BGI's website at a now-broken URL. The document appears to be incomplete, as it is missing the footnotes. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by BGI, which Respondents offer for the truth and attribute to a party that did not testify in this proceeding. Given the inherent unreliable nature of the document, it lacks probative value (*see* Rule 4.43(b)). This court should disregard RX3062. Respondents elected not to pursue any form of discovery from BGI in this action, likely because they know such evidence would not support their contention that BGI will be a feasible alternative NGS platform available to MCED developers in the United States any time in the foreseeable future. Indeed, Illumina has obtained discovery from BGI on this very topic in another proceeding, prompting the court to conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022) (noting the deposition testimony of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

[redacted]

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding Natera's test development. This Court should disregard this evidence.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed

publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

653. Ariosa (at the time part of Roche) switched its Harmony non-invasive prenatal test from an NGS-based approach to a microarray-based approach, and claimed to have achieved lower cost and decreased turnaround time for the test. (PX7096 (Song (Omniome) Dep. at 124–28); RX3400 (Juneau et al., 2014).) Ariosa completed this platform switching without interrupting the commercial availability of the Harmony test. (PX7096 (Song (Omniome) Dep. at 125–26).)

Response to Finding No. 653

Complaint Counsel objects to the proposed finding because it cites unreliable testimony and is misleading, it does not cite Dr. Cote as the true source of this purported fact, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding cites to deposition testimony for which Respondents asked an improper leading question to elicit the response. (PX7096 (Song (Omniome) Dep. at 125) ("Q. And you did succeed in making that conversion, didn't you?")). As such this statement is unclear, unreliable and should be disregarded.

The proposed finding is misleading because it concerns a non-invasive prenatal test (and provides zero technical details about that test), not an MCED test. NIPT is a different application than MCED, and the purported fact that one NIPT test was able to be switched from an NGS platform to a microarray platform is not evidence that any MCED test at issue in the present matter could be performed on a microarray.

The proposed finding is misleading because it suggests that Ariosa changed its NIPT test from running on an NGS platform to running on a microarray platform because there were

advantages to microarrays. [redacted]

The proposed finding is misleading because it implies that Ariosa's transfer of its NIPT test to a microarray platform did not impact the quality of the test. In fact, Dr. Song testified that "in terms of the plans that we had, had we stayed on an NGS platform, we were not able to further make those development efforts on the array-based platform." (PX7096 (Song (Omniome) Dep. at 125)).

The proposed finding is against the weight of the evidence that microarrays do not work for MCED testing (*see* CCFF ¶¶ 1407-40). Moreover, Dr. Song testified that Ariosa abandoned its plans for developing oncology tests because ctDNA was not detectable on a microarray. (PX7071 (Song (Omniome) IHT at 98–99)). Dr. Song also testified that detecting ctDNA was "beyond the technical possibilities of an array system" because microarrays do not have the level of sensitivity necessary to detect rare events such as ctDNA. (PX7071 (Song (Omniome) IHT at 99)).

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is taken nearly verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 343) and represents only his opinion rather than market realities. Moreover, it is misleading because Respondents do not attribute the purported fact to Dr. Cote as the source. Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS

platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across these subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

654. [redacted]

Response to Finding No. 654

[redacted]

[redacted]

[redacted]

654.1 [redacted]

Response to Finding No. 654.1

[redacted]

[redacted]

[redacted]

654.2 [redacted]

Response to Finding No. 654.2

[redacted]

[redacted]

655. In addition, a test developer may develop its test on one platform, but choose to commercialize on another. (RX3869 (Cote Expert Report) ¶ 345.) [redacted]

Response to Finding No. 655

[redacted]

[redacted]

[redacted]

656. Even if switching requires a more substantial change, for example in capture technology or a different/unfamiliar sequencing chemistry, in light of the long way multi-cancer screening tests have to go before commercialization, the time to switch is unlikely to meaningfully affect the test developer's timeline. (Cote Tr. 3776.)

Response to Finding No. 656

Complaint Counsel objects to the proposed finding because it is unsupported, vague, speculative, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is unsupported because the source cited (Cote Tr. 3776) does not discuss or relate to "capture technology" or "different/unfamiliar sequencing chemistry."

The proposed finding is vague because it does not explain what "a more substantial change" is in relation to. The proposed finding is also vague because it does not define "capture technology," or "different/unfamiliar sequencing chemistry." It also does not explain what is meant by "in light of the long way multi-cancer screening tests have to go before commercialization" or what it means to "meaningfully affect" the test developer's timeline.

The proposed finding is inherently speculative. For support, Respondents cite only paid testimony of a purported expert (Cote Tr. 3776) that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the base conjecture, this proposed finding of fact should be disregarded.

Moreover, Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing

MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

> 656.1 For example, it took approximately nine months for Dr. Cote's lab to revalidate the AML clinical trial exome assay to use a different library prep and exome capture reagent, while transitioning from HiSeq to NovaSeq, with substantially different sequencing chemistry. (RX3869 (Cote Expert Report) ¶ 346; Cote Tr. 3774–75.)

Response to Finding No. 656.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, speculative, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not define the "AML clinical trial exome assay."

The proposed finding is misleading because it discusses a test that is not a liquid biopsy assay and not an MCED test. Evidence related to purportedly switching a non-MCED non-liquid

biopsy test from one Illumina sequencer to another does not provide support for the time it would take to switch an MCED test from an Illumina NGS instrument to a non-Illumina NGS instrument.

Complaint Counsel agrees that even for a test that is not a liquid biopsy assay and not an MCED test, switching NGS platforms (even from one Illumina platform to another) still requires many months of effort.

[redacted]

[redacted]

[redacted]

2. **Expectations**

657. Although it cannot be estimated precisely how long it would take for a multi-cancer screening test to switch between an Illumina platform and a third party sequencing platform, for example, the length of time required would likely depend on a number of factors including whether clinical trials are required, the laboratory process, and access to validation scientists and clinical samples. (RX3869 (Cote Expert Report) ¶ 347.)

Response to Finding No. 657

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not refer to any specific "multi cancer screening test" and does not refer to any specific "third party sequencing platform." The proposed finding is also vague because it does not explain what types of "clinical trials" it is referring to. It is also vague because it does not list all of the factors that the length of time purportedly depends on.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted nearly verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

[redacted]

[redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

658. Assuming no clinical trials are required, a test developer may need to conduct a revalidation study (which is estimated to take 6–12 months) potentially followed by a bridging or comparison study (which can take up to one month). (Aravanis (Illumina) Tr. 1865.) In the re-validation stage, a test developer needs to repeat the analytical studies on a new NGS platform. (RX3869 (Cote Expert Report) ¶ 348.)

Response to Finding No. 658

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it begins with "[a]ssuming no clinical trials are required" but does not explain the basis for that assumption. The proposed finding is vague because it does not define "revalidation study" or "bridging or comparison study." The proposed finding is also vague because it does not specific what test or type of test is it referring to, nor does it identify the purported "new NGS platform" it references.

The proposed finding is misleading because it assumes a test developer undertaking to switch an MCED test to a new NGS platform would be able to immediately commence an analytical validation study. This is against the weight of substantial evidence showing that that a very significant amount of work would precede the point of even commencing a final analytical validation [redacted] For example, [redacted]

[redacted]

[redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted nearly verbatim from Dr. Cote's report and

represents only his opinion rather than market realities.

The proposed finding is also misleading because, although Dr. Cote cited no support for this statement in his report (RX3869 (Cote Expert Report) ¶ 348), Respondents now fill in that hole by citing self-serving trial testimony from Illumina executive Alex Aravanis as the primary source for this purported fact. To be clear, *first* Dr. Cote wrote a report that ignored market realities in order to craft a narrative that fit Respondents' case, *then* Respondents generated this testimony on demand since they could not find support in the form of reliable evidence such as ordinary course documents and unbiased witness testimony.

This proposed finding is inherently speculative. For support, Respondents cite only to the self-serving testimony of Illumina executive Alex Aravanis and the paid testimony of Dr. Cote that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the witnesses' base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted] Therefore, this Court should disregard the proposed finding.

659. Dr. Cote estimates that re-validating a test on a new NGS platform, if successful, would take approximately 6–12 months. (Cote Tr. 3774–75.) For a test developer to re-validate its test on a new NGS instrument, it would need to show that the performance of the test on the new machine was appropriate and similar to the performance using Illumina's machine. (RX3869 (Cote Expert Report) ¶ 348; Cote Tr. 3773.)

Response to Finding No. 659

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not define "re-validating" or "bridging or comparison study" and does not explain what "appropriate and similar" means. The proposed finding is also vague because it does not specific what test or type of test is it referring to, nor does it identify the purported "new NGS platform" it references.

The proposed finding is misleading because it assumes a test developer undertaking to switch an MCED test to a new NGS platform would be able to immediately commence an analytical validation study. This is against the weight of substantial evidence showing that that a very significant amount of work would precede the point of even commencing a final analytical validation [redacted] For example, [redacted]

[redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted nearly verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

660. For an LDT test not approved by the FDA, switching NGS platforms or technical modalities is fairly straightforward. (RX3869 (Cote Expert Report) ¶ 349.) The test developer merely needs to complete the technical development, and then conduct a validational, case-control study using previously collected samples or freshly collected sample. (RX3869 (Cote Expert Report) ¶ 349.)

Response to Finding No. 660

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not define "technical modalities," "technical development," or "validational case-control study." and it is not clear what "fairly straightforward" means. The proposed finding is also vague because it does not specific what test or type of test is it referring to, nor does it identify the purported "NGS platforms" it references.

The proposed finding is misleading because, what Dr. Cote characterizes as "the test developer *merely* needs to complete the technical development" is in fact a monumental undertaking. Dr. Cote simply assumes with no basis that a test developer undertaking to switch an MCED test to a new NGS platform would be able to immediately commence an analytical validation study. This is against the weight of substantial evidence showing that that a very significant amount of work would precede the point of even commencing a final analytical validation [redacted] For example, [redacted]

[redacted]

[redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

661. Dr. Cote expects that most test developers who are already working on or have validated a test will have access to banks of clinical samples (used for that validation), which can be revalidated retrospectively for these purposes in relatively short order. (RX3869 (Cote Expert Report) ¶ 349.)

Response to Finding No. 661

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not define "validated" or "validation" and it does not explain what "revalidated retrospectively for these purposes" means. It is also imprecise and unclear as to what is meant by "in relatively short order."

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted practically verbatim from Dr. Cote's report and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

662. For an IVD test approved by the FDA, if the clinical testing portion of the IVD test has changed since the clinical trial demonstrating its efficacy, the FDA requires the IVD sponsor to provide data from a bridging or comparison study to demonstrate that the new clinical test using the third party NGS platform "has performance characteristics that are very similar to those of the test that was used in the trial," *i.e*, using the Illumina platform. (Cote Tr. 3776; RX3218 (FDA) at 30).)

Response to Finding No. 662

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not explain what "the clinical testing portion of the IVD test" means. It is also does not define or explain what "bridging or comparison study" means. It is also vague because it does not identify the purported "third party NGS platform" it references.

[redacted]

[redacted] For example, [redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted practically verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 350), even though Respondents do not even cite his report in the proposed finding, and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

663. The performance similarity is often demonstrated in a bridging or comparison study by performing the new test using original clinical trial samples and a pre-specified statistical analysis plan, thereby showing both concordance and discordance between the two tests using the same specimens. (RX3218 (FDA) at 30.)

Response to Finding No. 663

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it is not clear what "the performance similarity" refers to. The proposed finding also does not define or explain what "bridging or comparison study," "original clinical trial samples," "pre-specified statistical analysis plan," "concordance," or "discordance" mean.

The proposed finding is misleading because Dr. Cote claims the FDA would simply require a "bridging or comparison study" as opposed to a new clinical trial. There is no basis for this assumption and it is against the weight of the evidence showing that switching an FDA-approved test to a new NGS platform would necessitate conducting a lengthy equivalency study and possibly new clinical trials [redacted] For example, [redacted]

[redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 350), even though Respondents do not even cite his report in the proposed finding, and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

> 663.1 Such a requirement also means that a costly new clinical trial need not be conducted: the IVD sponsor just need to run the new test on the already collected sample to show consistent results. (RX3869 (Cote Expert Report) ¶ 350.) If the results of the bridging or comparison study demonstrate that the two platforms lead to equivalent performance, no additional clinical trials may be required. (RX3869 (Cote Expert Report) ¶ 350.)

Response to Finding No. 663.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague as to what "such a requirement" and "already collected

sample" refers to. The proposed finding also does not define or explain what constitute "consistent results" or "equivalent performance."

The proposed finding is misleading because Dr. Cote claims the FDA would simply require a "bridging or comparison study" as opposed to a new clinical trial. There is no basis for this assumption and it is against the weight of the evidence showing that switching an FDA-approved test to a new NGS platform would necessitate conducting a lengthy equivalency study and possibly new clinical trials [redacted] For example, [redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869

(Cote Report) ¶ 350) and represents only his opinion rather than market realities.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

664. Dr. Cote estimates that conducting the bridging or comparison study—including a repeatability study—would take approximately one month to complete. (Cote Tr. 3773.) It would cost approximately $1 million to $2 million if samples need to be purchased. (Cote Tr. 3775.) [redacted] The time and cost of these bridging or comparison studies are both relatively low compared to overall development time and cost for clinical tests. (PX7065 (Aravanis (Illumina) IHT at 164–66); [redacted]

Response to Finding No. 664

[redacted]

[redacted]

[redacted]

[redacted]

665. If the results generated by the two systems were not substantially equivalent, the clinical studies might have to be repeated on the alternative platform. (RX3869 (Cote Expert Report) at 174.) If new clinical trials are required, or if the bridging or comparison study does not show that the Illumina platform and the third-party platform are equivalent, new large-scale clinical trials may be required, which would require a lengthier process and would be in addition to the revalidation process discussed in above. (RX3869 (Cote Expert Report) ¶ 352.)

Response to Finding No. 665

Complaint Counsel objects to the proposed finding because it is vague, misleading, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague as to what "the results generated by the two systems," "the clinical studies," or "revalidation process discussed in [sic] above" refer to. The proposed finding is also vague because it does not define or explain what constitute "substantially equivalent" means. The proposed finding is also vague because it is unclear what "a lengthier process" means.

The proposed finding is misleading because Dr. Cote claims clinical studies "might" have to be repeated on the alternative platform. This is against the weight of the evidence showing that switching an FDA-approved test to a new NGS platform would necessitate conducting a

lengthy equivalency study and possibly new clinical trials [redacted] For example, [redacted]

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 352) and represents only his opinion rather than market realities.

The proposed finding is also against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

665.1 The chance for a bridging or comparison study failing to show the Illumina platform and the third-party platform to be equivalent is very low, because given the comparable accuracy of the third-party platforms, they should be able to accurately reproduce the sequence obtained using the Illumina platform. (Cote Tr. 3775–76; RX3869 (Cote Expert Report) ¶ 352.)

Response to Finding No. 665.1

Complaint Counsel objects to the proposed finding because it is vague, misleading, speculative, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague as to what "the comparable accuracy of the third-party platforms" means. The proposed finding is also vague because it does not define the "bridging or comparison study" or the standard for what it means to "accurately reproduce" the sequence obtained using the Illumina platform.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 352) and represents only his opinion rather than market realities.

The proposed finding's claim that there is a "very low" chance that the undefined bridging study would fail given the comparable accuracy of the third party platforms amounts to nothing more than rank speculation by Dr. Cote. Respondents and Dr. Cote conveniently assume that other sequencing platforms have comparable accuracy, citing zero evidence, while ignoring the weight of contrary evidence. For example, [redacted]

[redacted]

The proposed finding is also against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or

experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

[redacted] Therefore, this Court should disregard the proposed finding.

666. Another factor which will likely determine the length of time a company would need to adapt its test to a new supplier is the way the test was developed. (RX3869 (Cote Expert Report) ¶ 353.) Tests may be developed based on more than one platform. (RX3869 (Cote Expert Report) ¶ 353.)

Response to Finding No. 666

Complaint Counsel objects to the proposed finding because it is vague and unsupported, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague in its use of the phrase "the way the test was developed."

The proposed finding is unsupported in that it provides no reliable evidence for the claim that tests may be developed based on more than one platform. The only source cited is Dr. Cote's expert report. This is insufficient, as it is not this Court's job to go dig into Dr. Cote's report and discern what if any actual documentary or testimonial evidence *from fact witnesses* may be listed there. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should decline Respondents' invitation to do their work for them and disregard this evidence. Incidentally, the one flimsy piece of evidence Dr. Cote cites in ¶ 353 of his report is addressed in Complaint Counsel's Responses to RPFF ¶¶ 667-68, below.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.g

667. Singlera has publicly stated that its test is compatible with both Illumina and Thermo Fisher NGS systems. RX3637 (Singlera) at 6.)

Response to Finding No. 667

Complaint Counsel objects to the proposed finding because it misattributes the source of a document and is against the weight of the evidence.

Complaint Counsel objects to the attribution of RX3637 (which Respondents purportedly captured from Singlera's website) to Singlera as the source of the document (it was not produced by Singlera), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document constitutes hearsay. It is an untested statement, which Respondents offer for the truth. Given the inherent unreliable nature of the documents, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is against the weight of the evidence showing that Singlera's PanSEER MCED test cannot be run on Thermo Fisher's platform. Singlera's Co-Founder and former CEO, Dr. Gary Gao, testified at trial that Singlera evaluated Thermo Fisher but concluded it was not an alternative: "Q. Has Singlera evaluated the use of NGS technology from any other vendor? A. Of course, you know, we always try to seek for alternative, like Thermo Fisher and other company, but … we evaluate it, it's not going to be a viable alternative. We are not sure even this product line will be continued. They are also not FDA-approved or FDA-cleared. Q.

Does Singlera currently have plans to switch to a Thermo Fisher NGS platform? A. No." (Gao (Singlera) Tr. 2894). This Court should disregard the proposed finding.

668. Singlera notes that its PanSeer assay is "compatible with the two leading next-generation sequencing platforms on the market (systems from Illumina such as the MiSeq or NextSeq as well as from Thermo Fisher Scientific including the Ion Torrent S5) any laboratory familiar with NGS library construction can quickly implement this method". (RX3637 (Singlera) at 6.) Therefore, switching between these two NGS suppliers would not be likely to require any significant time to adapt the technology for that developer. (RX3869 (Cote Expert Report) ¶ 353.)

Response to Finding No. 668

Complaint Counsel objects to the proposed finding because it misattributes the source of a document, is against the weight of the evidence, it is speculative, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

Complaint Counsel objects to the attribution of RX3637 (which Respondents purportedly captured from Singlera's website) to Singlera as the source of the document (it was not produced by Singlera), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. The document constitutes hearsay. It is an untested statement, which Respondents offer for the truth. Given the inherent unreliable nature of the documents, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is against the weight of the evidence showing that Singlera's PanSEER MCED test cannot be run on Thermo Fisher's platform. Singlera's Co-Founder and former CEO, Dr. Gary Gao, testified at trial that Singlera evaluated Thermo Fisher but concluded it was not an alternative: "Q. Has Singlera evaluated the use of NGS technology from any other vendor? A. Of course, you know, we always try to seek for alternative, like Thermo Fisher and other company, but … we evaluate it, it's not going to be a viable alternative. We are not sure even this product line will be continued. They are also not FDA-approved or FDA-cleared. Q.

Does Singlera currently have plans to switch to a Thermo Fisher NGS platform? A. No." (Gao (Singlera) Tr. 2894).

The proposed finding is speculative because, from the first purported fact (based on out-of-context, untested hearsay) in the proposed finding, Respondents make an extraordinary unfounded leap and infer that "[t]herefore, switching between these two NGS suppliers would not be likely to require any significant time to adapt the technology." To be clear, Dr. Gao's trial testimony established that Singlera *cannot use* the Thermo Fisher NGS platform for its PanSEER MCED test. Yet Respondents claim not only that Singlera *can* use the Thermo platform, but also that it would take no time to switch, citing nothing other than rank speculation by their paid purported multi subject expert Dr. Cote. This does not withstand basic scrutiny.

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 353) and represents only his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding running Singlera's PanSEER test (or developing any MCED test on any platform), much less switching PanSEER from Illumina's NGS platform to Thermo's. This Court should disregard this evidence.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

669. Natera and BGI Genomics formed a partnership and has now launched the Signatera in China "that incorporates MGI sequencing platforms." (RX3062 (BGI) at 1.) Neither Natera nor BGI has complained about any difficulty switching from Illumina's HiSeq to BGI's NGS platform. (RX3499 (Natera) at 6); (RX3869 (Cote Expert Report) ¶ 354.)

Response to Finding No. 669

Complaint Counsel objects to the proposed finding because it misattributes the source of a document, it cites unreliable hearsay, it is vague, misleading, unsupported, and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

Complaint Counsel objects to the attribution of RX3062 to BGI as the source of the document, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3.

RX3062 appears to be a document Respondents purportedly captured from BGI's website at a now-broken URL. The document appears to be incomplete, as it is missing the footnotes. The document itself constitutes unreliable hearsay. It is an untested statement, not produced by BGI, which Respondents offer for the truth and attribute to a party that did not testify in this proceeding. Given the inherent unreliable nature of the document, it lacks probative value (*see* Rule 4.43(b)). This court should disregard RX3062. Respondents elected not to pursue any form of discovery from BGI in this action, likely because they know such evidence would not support their contention that BGI will be a feasible alternative NGS platform available to MCED developers in the United States any time in the foreseeable future. Indeed, Illumina has obtained discovery from BGI on this very topic in another proceeding, prompting the court to conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022) (noting the deposition testimony of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

The proposed finding is vague because it does not define or identify "MGI sequencing platforms."

The proposed finding is misleading because it implies that BGI is running Natera's Signatera assay on BGI's sequencing platform in China. This is unsupported and against the weight of the evidence. [redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is merely copied and pasted verbatim from Dr. Cote's report and

represents only his opinion rather than market realities.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as support for purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge regarding Natera's test development. This Court should disregard this evidence.

[redacted] Therefore, this Court should disregard the proposed finding.

670. Ariosa switched its Harmony NIPT test from an NGS-based approach to a microarray-based approach, and claimed to have achieved lower cost and decreased turnaround time for the test. (PX7096 (Song (Omniome) Dep. at 124–28); RX3400 (Juneau et al., 2014).)

Switching for the Harmony test, which is an LDT, required only a bridging study; no additional clinical trials were needed. (RX3869 (Cote Expert Report) ¶ 355.)

Response to Finding No. 670

Complaint Counsel objects to the proposed finding because it cites unreliable testimony, is unsupported, and is misleading, and Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading because it concerns a non-invasive prenatal test (and provides zero technical details about that test), not an MCED test. NIPT is a different application than MCED, and the purported fact that one *NIPT test* was able to be switched from an NGS platform *to a microarray platform* is not evidence of the requirements for switching an *MCED test* from an Illumina NGS platform *to a different NGS platform*.

The proposed finding cites to deposition testimony for which Respondents asked an improper leading question to elicit the response. (PX7096 (Song (Omniome) Dep. at 125) ("Q. And you did succeed in making that conversion, didn't you?")). As such this statement is unclear, unreliable and should be disregarded.

The proposed finding is unsupported in that it provides no reliable evidence for the claim that switching the Harmony test required "only a bridging study; no additional clinical trials." The only source cited is Dr. Cote's expert report. This is insufficient, as it is not this Court's job to go dig into Dr. Cote's report and discern what if any actual documentary or testimonial evidence *from fact witnesses* may be listed there. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding any studies Ariosa conducted (or developing an

MCED test on any platform). This Court should decline Respondents' invitation to do their work for them and disregard this evidence.

The proposed finding is misleading because it suggests that Ariosa changed its NIPT test from running on an NGS platform to running on a microarray platform because there were advantages to microarrays. [redacted]

The proposed finding is misleading because it implies that Ariosa's transfer of its NIPT test to a microarray platform did not impact the quality of the test. In fact, Dr. Song testified that "in terms of the plans that we had, had we stayed on an NGS platform, we were not able to further make those development efforts on the array-based platform." (PX7096 (Song (Omniome) Dep. at 125)).

The proposed finding is against the weight of the evidence that microarrays do not work for MCED testing [redacted] Moreover, Dr. Song testified that Ariosa abandoned its plans for developing oncology tests because ctDNA was not detectable on a microarray. (PX7071 (Song (Omniome) IHT at 98–99)). Dr. Song also testified that detecting ctDNA was "beyond the technical possibilities of an array system" because microarrays do not have the level of sensitivity necessary to detect rare events such as ctDNA. (PX7071 (Song (Omniome) IHT at 99)).

The proposed finding is also misleading because—like numerous of Respondents' other

proposed findings—it is taken nearly verbatim from Dr. Cote's report and represents only his opinion rather than market realities. [redacted] Therefore, this Court should disregard the proposed finding.

670.1 For the bridging study, Ariosa conducted a case-control study with 878 maternal venous blood samples, 486 samples had been originally tested using Harmony, and 392 samples were freshly collected for the study. (RX3400 (Juneau et al., 2014) at 2.) [redacted]

Response to Finding No. 670.1

[redacted]

[redacted]

[redacted]

671. Companies routinely conduct bridging or comparison studies for modifications of their clinical oncology tests. (RX3869 (Cote Expert Report) ¶ 356.) [redacted]

Response to Finding No. 671

[redacted]

[redacted]

[redacted]

672. When Roche initiated its EURTAC study for the correlation between EGFR activating mutations and Non–Small-Cell Lung Cancer (NSCLC), the test utilized Sanger sequencing, then confirmed by fragment length analysis and Taqman assay for two mutations. (RX3057 (Benlloch et al., 2014) at 3.)

Response to Finding No. 672

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it represents Dr. Cote's opinion testimony (though unattributed), Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading because it concerns a tumor tissue test, not a liquid biopsy test. (RX3057 (Benlloch et al., 2014) at 3 (describing "FFPET specimens," which are

tumor tissue samples). The proposed finding is also misleading because it concerns a companion diagnostic test, not an MCED test. (RX3057 (Benlloch et al., 2014) at 1 ("We sought to validate … a companion diagnostic assay[.]"). The proposed finding is also misleading because it involves modifying a test that utilized Sanger sequencing to instead utilize a multiplex allele-specific PCR-based assay, not switching an MCED test from an Illumina NGS system to an alternative NGS system. (RX3057 (Benlloch et al., 2014) at 2-3 (The "cobas *EGFR* Mutation Test … is a … multiplex allele-specific PCR-based assay designed to detect 41 mutations exons 18, 19, 20, and 21 in [tumor tissue] specimens of human [non-small cell lung cancer]."). Allele-specific PCR, as the name implies, can only detect known mutations. The purported fact that a tumor tissue companion diagnostic test for a small number of known mutations switched from using Sanger sequencing to using multiplex PCR is simply not evidence of the requirements for switching an MCED liquid biopsy test from an Illumina NGS platform to an alternative NGS platform.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

The proposed finding is also misleading because—like numerous of Respondents' other

proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 356), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. [redacted] Therefore, this Court should disregard the proposed finding.

672.1 Roche developed a multiplex PCR-based cobas® EGFR Mutation Test of 41 *EGFR* mutations after patients had been screened and enrolled in EURTAC study using the previous LDT. (RX3221 (FDA) at 28.)

Response to Finding No. 672.1

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it misattributes the source of a document, it represents Dr. Cote's opinion testimony (though unattributed), Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

Complaint Counsel objects to the attribution of RX3221 to the FDA as the source of the document (it is unclear where Respondents obtained the document, but it was not produced by the FDA), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading because it concerns a tumor tissue test, not a liquid biopsy test. (RX3057 (Benlloch et al., 2014) at 3 (describing "FFPET specimens," which are tumor tissue samples). The proposed finding is also misleading because it concerns a companion diagnostic test, not an MCED test. (RX3057 (Benlloch et al., 2014) at 1 ("We sought to validate … a companion diagnostic assay[.]"). The proposed finding is also misleading because it involves modifying a test that utilized Sanger sequencing to instead utilize a multiplex allele-specific PCR-based assay, not switching an MCED test from an Illumina NGS system to an alternative NGS system. (RX3057 (Benlloch et al., 2014) at 2-3 (The "cobas *EGFR* Mutation Test … is a … multiplex allele-specific PCR-based assay designed to detect 41 mutations exons 18, 19, 20, and 21 in [tumor tissue] specimens of human [non-small cell lung cancer]."). Allele-specific PCR, as the name implies, can only detect known mutations. The purported fact that a tumor tissue companion diagnostic test for a small number of known mutations switched from using Sanger sequencing to using multiplex PCR is simply not evidence of the requirements for switching an MCED liquid biopsy test from an Illumina NGS platform to an alternative NGS platform.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. [redacted]

[redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 356), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. [redacted] Therefore, this Court should disregard the

proposed finding.

> 672.2 A retrospective bridging study was conducted to test tissue specimens already collected from the EURTAC study patients using the cobas® EGFR Mutation Test, and the EURTAC study results with the previous LDT data using Sanger sequencing and the bridging study results showing the concordance of the multiplex PCR-based cobas® EGFR Mutation Test results with the LDT supported the FDA approval of the cobas® EGFR Mutation Test. (RX3221 (FDA) at 28.)

Response to Finding No. 672.2

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it misattributes the source of a document, it represents Dr. Cote's opinion testimony (though unattributed), Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

Complaint Counsel objects to the attribution of RX3221 to the FDA as the source of the document (it is unclear where Respondents obtained the document, but it was not produced by the FDA), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading because it concerns a tumor tissue test, not a liquid biopsy test. (RX3057 (Benlloch et al., 2014) at 3 (describing "FFPET specimens," which are tumor tissue samples). The proposed finding is also misleading because it concerns a companion diagnostic test, not an MCED test. (RX3057 (Benlloch et al., 2014) at 1 ("We sought to validate … a companion diagnostic assay[.]"). The proposed finding is also misleading because it involves modifying a test that utilized Sanger sequencing to instead utilize a multiplex allele-specific PCR-based assay, not switching an MCED test from an Illumina NGS system to an alternative NGS system. (RX3057 (Benlloch et al., 2014) at 2-3 (The "cobas *EGFR* Mutation Test … is a … multiplex allele-specific PCR-based assay designed to detect 41 mutations exons

18, 19, 20, and 21 in [tumor tissue] specimens of human [non-small cell lung cancer].”). Allele-specific PCR, as the name implies, can only detect known mutations. The purported fact that a tumor tissue companion diagnostic test for a small number of known mutations switched from using Sanger sequencing to using multiplex PCR is simply not evidence of the requirements for switching an MCED liquid biopsy test from an Illumina NGS platform to an alternative NGS platform.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted]

Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

The proposed finding is also misleading because—like numerous of Respondents’ other proposed findings—it is copied and pasted verbatim from Dr. Cote’s report (RX3869 (Cote Report) ¶ 356), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote’s lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS

instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

672.3 The bridging study concluded that the "PCR test showed superior sensitivity and specificity compared with conventional Sanger sequencing." (RX3057 (Benlloch et al., 2014) at 2.)

Response to Finding No. 672.3

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it represents Dr. Cote's opinion testimony (though unattributed), Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is misleading because it concerns a tumor tissue test, not a liquid biopsy test. (RX3057 (Benlloch et al., 2014) at 3 (describing "FFPET specimens," which are tumor tissue samples). The proposed finding is also misleading because it concerns a companion diagnostic test, not an MCED test. (RX3057 (Benlloch et al., 2014) at 1 ("We sought to validate … a companion diagnostic assay[.]"). The proposed finding is also misleading because it involves modifying a test that utilized Sanger sequencing to instead utilize a multiplex allele-specific PCR-based assay, not switching an MCED test from an Illumina NGS system to an

alternative NGS system. (RX3057 (Benlloch et al., 2014) at 2-3 (The "cobas *EGFR* Mutation Test … is a … multiplex allele-specific PCR-based assay designed to detect 41 mutations exons 18, 19, 20, and 21 in [tumor tissue] specimens of human [non-small cell lung cancer]."). Allele-specific PCR, as the name implies, can only detect known mutations. The purported fact that a tumor tissue companion diagnostic test for a small number of known mutations switched from using Sanger sequencing to using multiplex PCR is simply not evidence of the requirements for switching an MCED liquid biopsy test from an Illumina NGS platform to an alternative NGS platform.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted] Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 356), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr.

Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

673. When Guardant expanded its Guardant360® CDx cancer therapy selection assay to also include testing of *EGFR* exon 19 deletions and two specific mutations, *EGFR* L858R, *EGFR* T790M for treatment of NSCLC using Tagrisso® (osimertinib), it conducted two bridging studies – one for adding the test for *EGFR* exon 19 deletions and the *EGFR* L858R mutation, and one for adding the test for the *EGFR* T790M mutation – using existing samples from the original clinical trials. (RX3223 (FDA) at 49.)

Response to Finding No. 673

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it misattributes the source of a document, it represents Dr. Cote's opinion testimony (though unattributed), Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

Complaint Counsel objects to the attribution of RX3223 to the FDA as the source of the document (it is unclear where Respondents obtained the document, but it was not produced by the FDA), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Given

the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading because it concerns a companion diagnostic test (which tests for a limited number of known mutations), not an MCED test (which screens for any mutations that may be present across large genomic regions). The proposed finding is also misleading because it involves modifying a test to screen for additional mutations while using the exact same Illumina NGS platform and method; it does not involve switching an MCED test from an Illumina NGS system to an alternative NGS system. (RX3223 at 2 Tbl. 1 (listing "*EGFR exon 19 deletions, L858R, and T790M**" mutations being added to panel), 3 Tbl. 2 (updated comprehensive list of all mutations contained in panel).) The purported fact that a companion diagnostic test (which assays a small number of known mutations) was updated to add a few additional mutations to the panel while continuing to run on the same Illumina NGS platform is simply not evidence of the requirements for *switching* an *MCED test* (which screens for unknown mutations across large genomic regions) from an Illumina NGS platform *to an alternative NGS platform*.

The proposed finding is also misleading because it does not even contain any information regarding the challenges, time, or costs associated with the purported bridging studies referenced.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted]

[redacted]

Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 357), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

674. FMI conducted a similar bridging study when it added testing of *NTRK* gene fusions for treatment of cancer patients with Vitrakvi® (larotrectinib) to its FoundationOne® CDx cancer therapy selection assay. (RX3240 (Roche/FMI) at 1–2.)

Response to Finding No. 674

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence, it misattributes the source of a document, it represents Dr. Cote's opinion testimony (though unattributed), Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

Complaint Counsel objects to the attribution of RX3240 (which Respondents appear to have captured from an FMI website) to Roche/FMI as the source of the document (the document was not produced by Roche/FMI), in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. Given the inherent unreliable nature of this document, it has little to no probative value. (*See* Rule 4.43(b)).

The proposed finding is misleading because it concerns a tumor tissue test, not a liquid biopsy test. (RX3240 at 1.) The proposed finding is also misleading because it concerns a companion diagnostic test (which tests for a limited number of known mutations), not an MCED test (which screens for any mutations that may be present across large genomic regions). The proposed finding is also misleading because it involves modifying a test to screen for additional mutations while using the exact same Illumina NGS platform and method; it does not involve switching an MCED test from an Illumina NGS system to an alternative NGS system. (RX3240 at 1 ("FoundationOne CDx … is now approved to detect NTRK1/2/3 fusions"), 2 (describing full panel covering variants in 324 genes).) The purported fact that a tissue based companion diagnostic test (which assays a small number of known mutations) was updated to add a few additional mutations to the panel while continuing to run on the same Illumina NGS platform is simply not evidence of the requirements for *switching* a *liquid biopsy MCED test* (which screens

for unknown mutations across large genomic regions) from an Illumina NGS platform *to an alternative NGS platform*.

The proposed finding is also misleading because it does not even contain any information regarding the challenges, time, or costs associated with the purported bridging study referenced.

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted]

Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 358), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about switching an MCED test from one NGS platform to another because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms

are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about switching an MCED test from Illumina's platform to a purported alternative platform is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

D. Distributable IVDs

675. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (RX3869 (Cote Expert Report) ¶ 359.)

Response to Finding No. 675

Complaint Counsel objects to the proposed finding because it is vague and against the weight of the evidence, it improperly cites expert testimony, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not identify the "several features" referenced. The proposed finding is also vague as to what "an appropriate option" means.

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as the only support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding developing an MCED test on any platform, much less determine whether to pursue a distributed kit IVD model for an MCED test. This Court should disregard this evidence.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about developing a distributed kit IVD version of an MCED test because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about developing distributed kit IVD versions of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

676. [redacted]

; PX0064 (Illumina) at 7.)

Response to Finding No. 676

[redacted]

677. [redacted]

Response to Finding No. 677

[redacted]

[redacted]

[redacted]

677.1 For customers who are performing cancer screening using a centralized model (as is the case with an LDT or a single-site PMA), the evidence suggests that customers will be likely to be able to achieve full capacity. (Goswami (Illumina) Tr. 3194–95.)

Response to Finding No. 677.1

Complaint Counsel objects to the proposed finding because it is vague and misleading, it represents Dr. Cote's opinion testimony (though unattributed), it is inherently speculative, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not identify any particular NGS platform, does not explain the type of "customers" referred to, and does not define "full capacity."

The proposed finding is misleading to the extent it suggests that customers performing cancer screening tests that may ultimately be offered as a distributed kit IVD model would not have sufficient testing volumes to operate their NGS platforms cost effectively. [redacted]

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 360), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities.

The proposed finding is also misleading because, although Dr. Cote cited no support for this statement in his report (RX3869 (Cote Expert Report) ¶ 360), Respondents now fill in that hole by citing self-serving trial testimony from Illumina executive Joydeep Goswami as the primary source for this purported fact. To be clear, *first* Dr. Cote wrote a report that ignored market realities in order to craft a narrative that fit Respondents' case, *then* Respondents generated this testimony on demand since they could not find support in the form of reliable evidence such as ordinary course documents and unbiased witness testimony.

This proposed finding is inherently speculative. For support, Respondents cite only to the self-serving testimony of Illumina executive Joydeep Goswami that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the witness's base conjecture, this proposed finding of fact should be disregarded.

Dr. Cote is not qualified to provide expert opinion testimony about developing a distributed kit IVD version of an MCED test because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about developing distributed kit IVD versions of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-

known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

677.2 In a distributed model, a small hospital or laboratory—precisely the types of customers who purportedly benefit from distributed kitted tests—are unlikely to be able to achieve the throughput necessary to make a NovaSeq Dx platform cost-effective. (Goswami (Illumina) Tr. 3194–95.) [redacted]

Response to Finding No. 677.2

[redacted]

[redacted]

[redacted]

678. In addition, with respect to distributable IVD test kits, there are several reasons why Illumina's position as a platform provider is relatively weaker with respect to distributable IVDs than in other areas. (RX3869 (Cote Expert Report) ¶ 361.)

Response to Finding No. 678

Complaint Counsel objects to the proposed finding because it is confusing, vague, and misleading, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is confusing because it begins with "[i]n addition."

The proposed finding is vague because the meaning of "Illumina's position as a platform provider" is unclear. The proposed finding is also vague because it does not define or explain what "relatively weaker" means and does not identify the "other areas" referred to.

The proposed finding is misleading because it is merely copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. Dr. Cote is not

qualified to provide expert opinion testimony about developing a distributed kit IVD version of an MCED test because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's opinion about developing distributed kit IVD versions of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

678.1 Illumina has not yet received clearance for NovaSeq Dx system. (Goswami (Illumina) Tr. 3194.) Illumina currently has regulatory clearance in the United States for the NextSeq Dx and MiSeq Dx systems. (Goswami (Illumina) Tr. 3191–92.) [redacted]; Nolan (Freenome) Tr. 2715; PX7112 (Bailey (PGDx) Dep. at 107).)

Response to Finding No. 678.1

[redacted]

[redacted]

[redacted]

678.2 If such developers were to pursue a distributable IVD kitted test for cancer screening, their test would need to be adapted to match the parameters of the NextSeq 550Dx, a system with different specifications from the RUO NovaSeq system. (RX3869 (Cote Expert Report) at 178.) [redacted]

Response to Finding No. 678.2

[redacted]

[redacted]

[redacted]

678.3 Because the evidence suggests that many sequencing platforms suitable for multi-cancer screening will become available in the next 1–2 years, test developers could validate their tests on an alternative NGS platform with regulatory clearance on a similar timeframe as validation on the (future) NovaSeq Dx platform. (RX3869 (Cote Expert Report) at 178.)

Response to Finding No. 678.3

Complaint Counsel objects to the proposed finding because it is vague, against the weight of the evidence, incorrect, and misleading, Dr. Cote is not qualified to offer expert opinion testimony on this subject, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is vague because it does not explain what "suitable" means in this context.

The proposed finding is against the weight of the evidence establishing that sufficient and timely entry of a new sequencing platform suitable for developing and commercializing an MCED test is unlikely. (*See* CCFF ¶¶ 1576-1731; Responses to RPFF ¶¶ 605-644, above). Moreover, there is zero evidence in the record that any new sequencer, much less one suitable for MCED testing, will obtain FDA clearance in the next 1-2 years.

The proposed finding is incorrect because it claims test developers could validate their

tests on an (unidentified) alternative NGS platform with regulatory clearance in a similar timeframe as on the "(future) NovaSeq DX platform." [redacted]

The proposed finding is against the weight of substantial evidence showing that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901; Responses to RPFF ¶¶ 645-74, above).

The proposed finding is misleading because—like numerous of Respondents' other proposed findings—it is copied and pasted verbatim from Dr. Cote's report (RX3869 (Cote Report) ¶ 362), even though Respondents do not attribute it to Dr. Cote, and represents only his opinion rather than market realities. Dr. Cote is not qualified to provide expert opinion testimony about developing a distributed kit IVD version of an MCED test because he has no experience developing MCED tests at all (*see* Response to RPFF ¶ 1960, below (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)) or about which NGS platforms are viable for MCED testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons (*see* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). Dr. Cote is also not credible (*see* Response to RPFF ¶ 1959, below (setting forth Dr. Cote's credibility problems across subjects). In addition, Dr. Cote's

opinion about developing distributed kit IVD versions of MCED tests is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight. Therefore, this Court should disregard the proposed finding.

678.4 [redacted] The NovaSeq instrument is a substantial investment. (Goswami (Illumina) Tr. 3189–91.)

Response to Finding No. 678.4

[redacted]

[redacted]

[redacted]

678.5 Most hospitals and independent laboratories would continue using the NextSeq Dx and may elect not to invest in a NovaSeq Dx for around $1 million, especially given the issues in meeting the requisite throughput by pooling samples. (Goswami (Illumina) Tr. 3194–95.) As of 2021, there are nearly 30,000 diagnostic and medical laboratory businesses in the U.S. (RX3174 (IBISWorld).) [redacted]

Response to Finding No. 678.5

[redacted]

[redacted]

[redacted]

[redacted]

V. COMPLAINT COUNSEL FAILED TO PROVE THE REQUISITE ANTITRUST MARKETS

A. The Alleged Relevant Market

1. Speculative and Simultaneously Over- and Under-Inclusive

a. The Alleged Relevant Market is Speculative

679. Complaint Counsel alleges an MCED market consisting of the Galleri test and any other test in development, so long as its developers contend that it will detect more than one cancer type and use NGS, no matter its anticipated features, functions, or launch timeline. (*See* FTC Pretrial Br. at 43–44; Compl. ¶ 3; PX6090 (Scott Morton Expert Report) ¶¶ 141–46.)

Response to Finding No. 679

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 20).

The proposed finding is also misleading, incorrect, and against the weight of the evidence to the extent Respondents allege Complaint Counsel has failed to properly define a relevant product market. [redacted] The appropriateness of this product market is overwhelmingly supported by the weight of the evidence. Evidence shows that MCED tests are not in the same product market as other blood-based oncology tests, like therapy selection, minimal residual disease ("MRD"), or diagnostic aid to cancer ("DAC") tests, because they serve a different function for a patient who cannot reasonably substitute them for an MCED test for

cancer screening. (*See* CCFF ¶¶ 611-33). Existing standard of care cancer screening tests, like mammograms and colonoscopies, are also not in the same product market as MCED tests because they perform a different function—provide a more invasive screen for later-stage, single cancers—and are not reasonable substitutes for an MCED test. (*See* CCFF ¶¶ 635-59). This distinction is even highlighted by Grail's own executives who highlighted that MCED tests are "very much to complement the standard screening approaches that are available today." (PX7103 (Jamshidi (Grail) Dep. at 38-39)). Finally, single-cancer liquid biopsy tests are also not in the same relevant product market as MCED tests because they also serve a different function by testing for more cancers simultaneously, as evidence from Respondents and other MCED developers makes clear. (*See* CCFF ¶¶ 660-87).

Evidence highlighting the competition and substitutability between MCED tests, including competition for pricing, features, testing methods, and accuracy, demonstrate these tests properly comprise a relevant product market. (*See* CCFF ¶¶ 668-830). The evidence clearly demonstrates that MCED developers, including Grail, view MCED tests as their own product market in which their products compete with each other. (*See* CCFF ¶¶ 746-808). Further, application of the *Brown Shoe* factors indicates a relevant product market exists for MCED tests, (*see* CCFF ¶¶ 688-821), as does the Hypothetical Monopolist Test as conducted Complaint Counsel's Expert, Dr. Fiona Scott Morton. (*See* CCFF ¶¶ 822-30).

680. This definition is impermissibly speculative. (PFF ¶¶ 680.1–680.5.)

Response to Finding No. 680

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely represented their own argument as a "fact."

680.1 [redacted] Gao (Singlera) Tr. 2925–26.)

Response to Finding No. 680.1

[redacted]

[redacted]

680.2 [redacted] Gao (Singlera) Tr. 2925–26.)

Response to Finding No. 680.2

[redacted]

[redacted]

680.3 [redacted]

Response to Finding No. 680.3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

680.4 [redacted]

Response to Finding No. 680.4

[redacted]

[redacted]

[redacted]

680.5 These "products" cannot be considered substitutes for Galleri. [redacted] 3727, 3777, 3782–83, 3814–15, [redacted]

Response to Finding No. 680.5

[redacted]

[redacted]

[redacted]

681. Numerous fact witnesses testified that the future contours of the MCED field were largely speculative or unknown:

Response to Finding No. 681

The proposed finding is unsupported because no evidence is cited for the factual proposition. The proposed finding is also vague and ambiguous because it refers to "numerous" fact witnesses without ***any*** witnesses and refers to the "future contours of the MCED field" without defining or otherwise provide any explanation of the MCED field. The proposed finding is also unsupported because no evidence is cited for the factual proposition. Therefore, this Court should disregard the proposed finding.

681.1 [redacted]

Response to Finding No. 681.1

[redacted]

[redacted]

[redacted]

[redacted]

681.2 [redacted]

Response to Finding No. 681.2

[redacted]

[redacted]

[redacted]

[redacted]

681.3 Dr. William Cance, Chief Medical Officer of the American Cancer Society, said it "would be very hard to even speculate" on how long it will be before there is a blood-based test that's sensitive and specific enough to replace the standard of care cancer screens available today. (PX7086 (Cance (ACS) Dep. at 51).)

Response to Finding No. 681.3

The proposed finding is misleading to the extent it is intended to imply that Dr. Cance testified that the MCED market is speculative. Dr. Cance was simply explaining it was speculative say when MCED tests would replace standard of care tests versus opining on the stage of any particular competitors or the market generally. (PX7086 (Cance (ACS) Dep. at 51). Indeed, Dr. Cance named Grail, Exact, and Freenome as some of the companies developing MCED tests in the United States. (Cance, Tr. 611-12). Therefore, this Court should disregard the proposed finding.

681.4 Quest's Kristie Dolan testified that "the field is too nascent to say with any level of specificity" whether MCED tests would compete with each other in the absence of identical capabilities. (PX7116 (Dolan (Quest) Dep. at 106).)

Response to Finding No. 681.4

The proposed finding is unreliable, misleading, against the weight of the evidence to the extent Respondents are suggesting MCED tests will not compete with each other in the future. The proposed finding is unreliable and misleading because the witness, Kristie Dolan from Quest Diagnostics, lacks the relevant experience and perspective to have the foundation to provide a probative opinion on competition in the MCED market. [redacted]

[redacted]

[redacted]

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

682. Because the proposed market does not exist, Complaint Counsel's economic expert admitted that she did not and could not consider any real world evidence regarding the pricing of MCED tests:

Response to Finding No. 682

The proposed finding is vague, confusing, unsupported, unreliable, incomplete, misleading, and incorrect. The proposed finding is vague and confusing because Respondents have not defined "real world evidence" or explained how that evidence relates to the "pricing" of MCED tests. Further, Respondents have not provided a single citation in support of their fact, thus rendering it unreliable, incomplete, and misleading. To the extent Respondents imply Complaint Counsel's expert, Dr. Fiona Scott Morton, did not support her conclusions with evidence about the MCED market from the evidentiary record, this finding is entirely incorrect as her report is replete with citations to testimony and documents from third parties and the parties discussing the MCED market. Therefore, this Court should disregard the proposed finding.

682.1 [redacted]

[redacted]

Response to Finding No. 682.1

[redacted]

682.2 [redacted]

Response to Finding No. 682.2

[redacted]

[redacted]

[redacted]

682.3 [redacted]

Response to Finding No. 682.3

[redacted]

[redacted]

682.4 [redacted]

Response to Finding No. 682.4

[redacted]

[redacted]

682.5 "Q. In forming your opinions, is it accurate to say that you did not consider data describing the past purchase patterns of consumers in their responses to price changes for MCED tests? A. As I have said, the MCED test was only launched a couple of months ago. We don't really have a setting in which consumers can do anything except [buy] Galleri in an uninsured fashion." (RX3852 (Scott Morton Dep. at 19).)

Response to Finding No. 682.5

[redacted]

[redacted]

683.

Response to Finding No. 683

[redacted]

683.1 She also did not attempt to fill the information gaps using surveys or other means, including information about the likely preferences and potential switching behavior of clinicians, patients, and payors related to the products she includes and excludes from her proposed MCED market. (RX6004 (Katz Trial Dep. at 17–22).)

Response to Finding No. 683.1

The proposed finding misrepresents Dr. Scott Morton's analysis. [redacted] The proposed finding is misleading to the extent it implies that an analysis of survey data is necessary to define the market. As Complaint Counsel explained in its Post-Trial Reply Brief, Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one. This is because the market, as most concepts in law or economics cannot be measured by metes and bounds. (Complaint Counsel's Post-Trial Reply Brief at Section I.). Moreover, the weight of the evidence – including the analysis of Dr. Scott Morton – shows that MCED tests are a relevant market. (CCFF § 3), *see also*, (Complaint Counsel's Post-Trial Reply Brief at Section I.B.).

683.2 Nor did she attempt to analyze likely substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. (RX6004 (Katz Trial Dep. at 17–22).)

Response to Finding No. 683.2

[redacted]

[redacted]

684. The evidence in the record demonstrates is that it is unlikely customers (*i.e.*, patients, doctors and payors) will view the products in development as substitutes with Galleri. (PFF ¶¶ 684.1–684.3.)

Response to Finding No. 684

[redacted]

CCFF ¶ 2426). Respondents own ordinary course documents analyze those core features and identify Grail's competitors today and those that it anticipates being substitutes in the future. *See, e.g.*, (CCFF, ¶¶ 2231-3284; 3294-3307; 3319-3325; 3335-3350; 3358-3361; 3370-3375; 3381-3384; 3395-3388; 3389-3393; 3424-3468; 3471-3492). Therefore, this Court should

disregard the proposed finding.

684.1 None of the tests in development has demonstrated the capability to detect 50 cancers. (*See* Lengauer (Exact/Thrive) Tr. 243, 260–61; [redacted] Gao (Singlera) Tr. 2874–75.)

Response to Finding No. 684.1

[redacted]

[redacted]

[redacted]

[redacted]

684.2 Nor has any test in development demonstrated the ability to identify cancer signal of origin without the aid of a PET-CT scan. (Lengauer (Exact/Thrive) Tr. 246–48; [redacted]); RX3115 (Chen et al 2020) at 6.)

Response to Finding No. 684.2

[redacted]

[redacted]

684.3 Determining the boundaries of Complaint Counsel's alleged market depends on a comparison to, or of, one or more non-existent tests. ([redacted]; Gao (Singlera) Tr. 2925–26.)

Response to Finding No. 684.3

[redacted]

[redacted]

685. As Dr. Katz testified, "[t]he timing of when [putative MCED developers are] going to actually have commercial products and when they're going to launch them and ultimately when [they are] going to get insurance coverage so that they have a chance of significant competitive success, . . . is highly uncertain and it's in the future." (RX6004 (Katz Trial Dep. at 34–35).)

Response to Finding No. 685

[redacted]

[redacted]

[redacted]

b. Simultaneously Over- and Under-Inclusive

686. [redacted] (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100.)

Response to Finding No. 686

[redacted]

[redacted]

[redacted]

687. [redacted]

[redacted] RX6004 (Katz, Trial Dep. at 30 ("[I] t's counterintuitive that a test, say, for testicular cancer should be out of the market because it's not a close enough substitute to a test that [detects] testicular cancer *and* prostate cancer" but that two hypothetical tests that detect "two completely nonoverlapping" cancer types are included "because they each do two").)

Response to Finding No. 687

[redacted]

[redacted]

688. In addition to clearly not being substitutes for *Galleri*, many of the tests in Complaint Counsel's proposed market are also not even substitutes with *each other*. (*See* RX6004 (Katz Trial Dep. at 29).)

Response to Finding No. 688

The proposed finding is only supported by improper expert testimony and should be disregarded in its entirety. This Court ordered Dr. Katz to confine his opinions to the opinions and bases for those opinions contained in Dr. Willig's expert witness report. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Dr. Katz's cited opinion does not appear to be contained in Dr. Willig's report in violation of this Court's order.

Complaint Counsel objects to Respondents proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] (Dr. Katz's materials considered lists three academic articles, six Illumina documents, three Grail documents, rebuttal report of Dr. Fiona Scott Morton as well as her trial testimony in reaching his initial conclusions that Dr. Willig did not cite nor list in his materials considered.) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Moreover, this finding is misleading. Respondents, however, do not specify which tests Dr. Katz is referring to and only mention a hypothetical postulated by their expert which appears unbased in the evidence of MCED test developers current or future plans. Finally, the proposed finding is irrelevant. [redacted]. Respondents yet again distract with the wrong question. The relevant antitrust question is not the competitiveness of the market participants with each other but rather their competitiveness with Grail. (*See* Complaint Counsel's Post-Trial Reply Brief at 24-28).

689. Complaint Counsel's proposed market would include any test that screens for two or more cancer types, even though that would necessarily group together screening tests that detect distinct cancer types in different populations. (*E.g.*, PX6090 (Scott Morton Expert Report) ¶¶ 141–42.)

Response to Finding No. 689

[redacted]

690. As Dr. Katz testified: "suppose we have two tests, one of which covers testicular cancer and prostate cancer . . . and then we have another one that does uterine cancer and ovarian cancer. It's really difficult for me to see how those could be substitutes for one another. I believe they're not. And I think that shows a fundamental defect in [Complaint Counsel's proposed] market." (RX6004 (Katz Trial Dep. at 29).)

Response to Finding No. 690

The proposed finding is based on improper expert opinion testimony and against the weight of the evidence. This Court ordered Dr. Katz to confine his opinions to the opinions and bases for those opinions contained in Dr. Willig's expert witness report. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute

expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Dr. Katz's cited opinion does not appear to be contained in Dr. Willig's report based on the proposed fact in violation of this Court's order and should be disregarded in its entirety.

Complaint Counsel also objects to Respondents proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] (Dr. Katz's materials considered lists three academic articles, six Illumina documents, three Grail documents, rebuttal report of Dr. Fiona Scott Morton as well as her trial testimony in reaching

his initial conclusions that Dr. Willig did not cite nor list in his materials considered.) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Finally, the proposed finding is against the weight of the evidence. As Complaint Counsel's Post-Trial Reply Brief outlines, Complaint Counsel has met its burden to prove a relevant market. (Complaint Counsel's Post-Trial Reply Brief at Section I.). Dr. Katz's assertion to the contrary is based on improper hypothetical unsupported by the realities of the market. Respondents do not point to any MCED test developers that intend to only commercialize MCED tests that meet Dr. Katz hypothetical. [redacted] Therefore, this Court should disregard the proposed finding.

> 690.1 Dr. Katz also testified that by defining the market to include tests that cannot be shown to be substitutes for Galleri or each other, Complaint Counsel's proposed market violates the narrowest market rule: "[Dr. Scott Morton] did not attempt to define the narrowest relevant market . . . that would pass the hypothetical [monopolist] test, and I believe this is a fact, that she did not explain or offer a justification for why that would be appropriate. And that's not something that's relying on testimony by other people. It's a failure of the logic and the form of analysis that she's applied." (RX6004 (Katz Trial Dep at 165–66).)

Response to Finding No. 690.1

The proposed finding is based on improper expert opinion testimony and against the weight of the evidence. This Court ordered Dr. Katz to confine his opinions to the opinions and bases for those opinions contained in Dr. Willig's expert witness report. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute

expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Dr. Katz's cited opinion does not appear to be contained in Dr. Willig's report as the proposed finding does not cite to any section of Dr. Willig's report and violates this Court's order and should be disregarded in its entirety.

Complaint Counsel also objects to Respondents proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] (Dr. Katz's materials considered lists three academic articles, six Illumina documents, three Grail documents, rebuttal report of Dr. Fiona Scott Morton as well as her trial testimony in reaching

his initial conclusions that Dr. Willig did not cite nor list in his materials considered.) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Moreover, Dr. Katz misstates the record in this case. Complaint Counsel did consider whether MCED tests were reasonably interchangeable. Complaint Counsel assessed the shared characteristics and uses of MCED tests that set them apart from other oncology tests; assessed whether MCED tests collectively are designed to target unique customers; and assessed whether MCED tests will have a distinct pricing apart from other oncology tests; and assessed industry recognition of MCEDs collectively. (Complaint Counsel's Post-Trial Brief at 57-63). Moreover, Dr. Katz misapplies the narrowest market principle. From the outset, the narrowest market principle can be helpful but is not required under the Horizontal Merger Guidelines. (PX7132, Willig Dep. 108). [redacted] Finally, Dr. Katz's unsupported, biased, and improper opinion is contravened by the weight of the evidence in this case that shows robust competition in this market. *See, e.g.*, [redacted] Therefore, this Court should disregard the proposed finding.

691. At the same time, Complaint Counsel's proposed market is also under-inclusive, because it excludes MCED tests that are not based on NGS technology.

Response to Finding No. 691

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their

own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 027). Moreover, Complaint Counsel has properly defined the market as explained in its Post-Trial Reply Brief. (Complaint Counsel's Post-Trial Reply Brief at Section I.).

692. It is undisputed that there are at least two MCED tests on the market that are not based on NGS technology. (PFF ¶¶ 692.1–692.2.)

Response to Finding No. 692

The proposed finding is unambiguously incorrect and should be wholly disregarded. Respondents cite to two of its own findings to support this alleged fact, yet neither reliably supports the assertion they make. As explained in the response below, [redacted] Further, Respondents' reliance on the second finding (PFF ¶ 692.2) also proves entirely uncredible. (*See* Response to RPFF ¶ 692.1, below). For this second finding, Respondents have only cited hearsay and their own expert report, in direct violation of the Court's order prohibiting the use of expert testimony to support factual assertions, thus rending this fact also unreliable and incorrect. Accordingly, this proposed finding should be disregarded as entirely incorrect, unreliable, and against the weight of the evidence.

692.1 StageZero's Aristotle test is a microarray-based liquid biopsy test that interrogates mRNA to detect 10 cancers. (Cote Tr. 3875–76; RX3171 (Dempsey et al., 2020); RX3869 (Cote Expert Report) ¶ 248.)

Response to Finding No. 692.1

This proposed finding should be wholly disregarded because it is entirely incorrect, against the weight of the evidence, and in direct violation of the Court's order prohibiting the use of expert testimony to support factual assertions. [redacted]

[redacted]

The finding is also misleading and vague because Respondents have not defined a "liquid biopsy test" or whether they're referring to an MCED cancer screening test. Furthermore, Respondents have relied exclusively on its own expert, Dr. Richard Cote, and an outdated article pulled from the internet to support this alleged finding despite having deposed a StageZero witness. This violation of the Court's order barring the use of expert testimony "to support factual propositions that should be established by fact witnesses or documents" also highlights more generally why Dr. Cote's opinions should `not be afforded any weight. (*See* Order on Post-Trial Briefing at 3). Dr. Cote is not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED testing, because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). As an unsupported and incorrect finding that unquestionably violates the Court's explicit order, this fact should be wholly disregarded.

692.2 Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (RX3259 (Genesys Biolabs); RX3869 (Cote Expert Report) ¶ 253.)

Response to Finding No. 692.2

This proposed finding should be wholly disregarded because it relies on hearsay and

evidence that is in direct violation of the Court's order prohibiting the use of expert testimony to support factual assertions. Respondent's first citation, a two-page article tagged RX3259 that they allege was collected from Genesys Biolabs according to the citation, was printed from the internet and lacks any information identifying its source. Further, the article cited (RX3259) does not mention the word proteomics or provide any information whatsoever about the platform of the test being discussed, let alone mention any connection to Genesys Biolabs. Respondents had ample opportunity to collect evidence from Genesys Biolabs, including issuing a subpoena to depose a relevant witness, yet failed to do so. Instead, Respondents have simply printed an article online and seek to admit evidence based on blatant hearsay.

As an alternative, Respondents have relied on the expert report of Dr. Richard Cote to support this assertion—a direct violation of the Court's order barring the use of expert testimony "to support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Briefing at 3). Dr. Cote is not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED testing, because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). As an unsupported and incorrect finding that unquestionably violates the Court's explicit order, this fact should be wholly disregarded.

693. Moreover, a number of companies are developing cancer screening tests that are not based on NGS technology, including tests in development from InterVenn Biosciences, PrognomiQ and Somalogic. (Leite (Illumina/InterVenn) Tr. 2171–74; RX3587 (PrognomiQ) at 2; RX3651 (Somalogic) at 1–7; RX3869 (Cote Expert Report) ¶¶ 247–67.)

Response to Finding No. 693

The proposed finding should be disregarded as impermissibly vague, misleading, unsupported, unreliable, and against the weight of the evidence. The proposed finding is vague

and misleading because Respondents state companies are developing "cancer screening tests" without specifying if these companies are developing MCED tests. In fact, Respondents only cite to evidence produced from one of these companies, testimony from InterVenn's John Leite, who explicitly testified that InterVenn is not developing an MCED test and is only developing single-cancer tests. (Leite (Illumina/InterVenn) Tr. 2178-81). For the other two companies, PrognomiQ and Somalogic, Respondents impermissibly rely on printed versions of website—unquestionably hearsay—and the expert report of Richard Cote. On top of being hearsay, the websites cited, RX3587 for PrognomiQ and RX3651 for Somalogic, don't even provide sufficient information about the design or platform for a cancer screening test, let alone whether these alleged cancer screening tests are MCED tests. Citations to Dr. Cote's report is in direct contravention of the Court's order barring the use of expert testimony "to support factual propositions that should be established by fact witnesses or documents," (*see* Order on Post-Trial Briefing at 3), and thus this finding should be wholly disregarded as unsupported and unreliable. Dr. Cote is also not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED testing, because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)).

The proposed finding is also against the weight of evidence that shows industry participants, including [redacted], repeatedly affirming Illumina's NGS platform is the only option for MCED developers. (*See* CCFF ¶¶ 1053-211). Further, the proposed finding is also vague and misleading because Respondents state "a number of companies" without quantifying a number or clarifying what they mean. Not only have Respondents failed to

provide reliable information about the three companies they mention in this finding, but they have similarly provided incorrect findings about [redacted] (*see* Response to RPFF ¶ 692.1), and a wholly unsupported finding about Genesys. (*See* Response to RPFF ¶ 692.2). As an unsupported and incorrect finding that unquestionably violates the Court's explicit order, this fact should be wholly disregarded.

693.1 These tests are too undeveloped to be included in a relevant market with Galleri. (Leite (Illumina/InterVenn) Tr. 2171–74; RX3587 (PrognomiQ) at 2; RX3651 (Somalogic) at 1–7.)

Response to Finding No. 693.1

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 28). Further, this proposed finding is impermissibly vague and misleading because Respondents have not defined "these tests" or provided sufficient information to understand their alleged "fact." To the extent Respondents are referring to tests alleged in development by InterVenn, PrognomiQ, and Somalogic, Respondents have failed to identify if these "tests' are in fact MCED tests. (*See* Response to RPFF ¶ 693). As such, and without more information, this proposed finding should be wholly disregarded as impermissibly vague, confusing, and entirely unsupported.

694. There is no evidence, or reason to believe, that an MCED test must use NGS technology to compete with GRAIL. (*See* Cance (ACS) Tr. 606; Cote Tr. 3729–30, 3736–37, 3872; RX3869 (Cote Expert Report) ¶ 75.)

Response to Finding No. 694

[redacted]

[redacted]

695. Nor is there any evidence, or reason to believe, that patients or doctors have any preference for an MCED test based on the platform used to run it. (*See, e.g.*, RX3852 (Scott Morton Dep. at 51).)

Response to Finding No. 695

The proposed finding misstates Dr. Scott Morton's testimony. Dr. Scott Morton actually testified that MCED tests are "broadly equivalent and there's gonna be a marketplace with multiple competitors in it, but all are going to meet this threshold of saving lives in the same

way." (RX3952 (Dr. Scott Morton Dep. at 51-52). [redacted] Further, the proposed finding is misleading to the extent that it implies that MCED test developers are not reasonable substitutes or that MCED test developers are not dependent on NGS platforms for the research, development, and commercialization of MCED tests. *See* Complaint Counsel Post-Trial Brief § II(E). Therefore, this Court should disregard the proposed finding.

696. What patients and doctors care about is whether a test works and for which indications, not how exactly it works. (*See, e.g.*, RX3852 (Scott Morton Dep. at 51) ("[U]ltimately the patient and the doctor are going to care about the ability of the test to prevent the disease and save lives.").)

Response to Finding No. 696

The proposed finding is misleading to the extent Respondents are implying that MCED test developers are not dependent on NGS sequencers for the research, development, and commercialization of MCED tests. [redacted] *see also*, Complaint Counsel's Post-Trial Brief at 68-79. Therefore, this Court should disregard the proposed finding.

2. **No Reasonable Interchangeability**

697. Not on the Market. At present, there is no product in existence that is reasonably interchangeable with GRAIL's Galleri test. (Bishop (GRAIL) Tr. 1401.)

Response to Finding No. 697

The proposed finding is vague, confusing, unsupported, against the weight of the evidence, misleading, incorrect, unreliable, and relies on self-serving testimony. The proposed finding is vague and confusing because Respondents have not identified what it means to be a "product in existence" or "reasonably interchangeable." To the extent the proposed finding

suggests there is no MCED test in development that is "reasonably interchangeable" with Grail's Galleri this finding is unsupported, misleading, against the weight of the evidence, and incorrect. There are numerous MCED test developers currently developing MCED tests that compete with Grail's Galleri, (*see* CCFF § VI), [redacted] Even Grail's former CEO, Hans Bishop—who Respondents cite to support this assertion—testified that there are several companies who have indicated an intent to develop a multicancer test, including Exact, Thrive, Guardant, Singlera, and Burning Rock. (CCFF ¶¶ 3200). The proposed finding is also unreliable because Respondents have only relied on the self-serving testimony of its own executive, Grail's former CEO Hans Bishop, who merely testified about his own views. The testimony that Respondents cite merely says that, "in his view," Mr. Bishop did not believe "Grail is competing today against any of these companies" that Respondent's counsel had asked him about. (*See* Bishop (GRAIL) Tr. 1401). [redacted] In the testimony cited, Mr. Bishop also never uses the term "reasonably interchangeable," which is a legal term that Respondents' counsel have tried to incorporate into his unrelated testimony. (*See* Bishop (GRAIL) Tr. 1401). Therefore, this Court should disregard the proposed finding.

698. Galleri is the only multi-cancer early detection test testing for anywhere near 50 cancer types on the market. (Bishop (GRAIL) Tr. 1401, [redacted]); Ofman (GRAIL) Tr. 3308; RX3852 (Scott Morton Dep. at 53); (Cance (ACS) Tr. 632–33).)

Response to Finding No. 698

[redacted]

[redacted]

[redacted]

[redacted]

699. Indeed, the prices and qualities of these yet-to-exist products are not even specified. (*See* PFF ¶¶ 750.1–750.4.)

Response to Finding No. 699

The proposed finding should be disregarded as impermissibly vague, misleading, unsupported, and thus unreliable. Respondents have failed to define "yet-to-exist products," much less "prices and qualities" of these undefined products, and have also provided no context

to understand their reference to "not even specified." Without defining or explaining any of these terms or references, the proposed finding is vague and misleading. As such, the proposed finding is similarly unsupported and unreliable. The proposed finding should thus be wholly disregarded.

700. Years Away. Most of the putative MCED developers identified by Complaint Counsel do not expect (and none can reasonably be expected) to launch a screening test for more than one cancer for many years. (PFF ¶¶ 701–706.)

Response to Finding No. 700

The proposed finding is vague, misleading, incomplete, incorrect, and against the weight of the evidence. The proposed finding is impermissibly vague and misleading because Respondents have made no effort to identify any specific MCED developers and have instead relied on vague language that says merely "*most* of the putative MCED developers" and "*many* years." These are subjective terms that do not provide sufficient support to provide anything probative. Without more information, this proposed finding is incomplete and not an alleged "fact."

[redacted]

- [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

701. Guardant. Guardant's LUNAR-2 product is being developed initially with an indication only for colorectal cancer. (Chudova (Guardant) Tr. 1154, 1179; [redacted] Thereafter, Guardant is prioritizing adding cancers with existing screening guidelines such as lung and breast cancer. (Chudova (Guardant) Tr. 1154.)

Response to Finding No. 701

[redacted]

701.1 [redacted]; Chudova (Guardant) Tr. 1154, [redacted].)

Response to Finding No. 701.1

[redacted]

701.2 [redacted]

Response to Finding No. 701.2

[redacted]

[redacted]

701.3 [redacted]

Response to Finding No. 701.3

[redacted]

701.4 [redacted]

[redacted]

Response to Finding No. 701.4

[redacted]

[redacted]

701.5 [redacted]

Response to Finding No. 701.5

[redacted]

[redacted]

701.6 [redacted]

Response to Finding No. 701.6

[redacted]

701.7 [redacted]

Response to Finding No. 701.7

[redacted]

[redacted]

702. [redacted]

Response to Finding No. 702

[redacted]

[redacted]

[redacted]

702.1 [redacted]

Response to Finding No. 702.1

[redacted]

[redacted]

702.2 [redacted]

Response to Finding No. 702.2

[redacted]

[redacted]

702.3 [redacted]

Response to Finding No. 702.3

[redacted]

[redacted]

[redacted]

702.4 [redacted]

Response to Finding No. 702.4

[redacted]

[redacted]

[redacted]

702.5 [redacted]

Response to Finding No. 702.5

[redacted]

[redacted]

702.6 [redacted]

[redacted]

Response to Finding No. 702.6

[redacted]

[redacted]

702.7 [redacted]

Response to Finding No. 702.7

[redacted]

[redacted]

[redacted]

702.8 [redacted]

Response to Finding No. 702.8

[redacted]

[redacted]

[redacted]

702.9 [redacted]

Response to Finding No. 702.9

[redacted]

[redacted]

[redacted]

702.10 [redacted]

Response to Finding No. 702.10

[redacted]

[redacted]

[redacted]

[redacted]

703. [redacted]

Response to Finding No. 703

[redacted]

[redacted]

[redacted]

703.1 [redacted]

Response to Finding No. 703.1

[redacted]

[redacted]

703.2 [redacted]

Response to Finding No. 703.2

[redacted]

[redacted]

703.3 [redacted]

Response to Finding No. 703.3

[redacted]

[redacted]

703.4 [redacted]

Response to Finding No. 703.4

[redacted]

[redacted]

703.5 [redacted]

Response to Finding No. 703.5

[redacted]

[redacted]

703.6 [redacted]

Response to Finding No. 703.6

[redacted]

[redacted]

[redacted]

703.7 [redacted]

Response to Finding No. 703.7

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[redacted]

[redacted]

703.8 [redacted]

Response to Finding No. 703.8

[redacted]

[redacted]

703.9 [redacted]

[redacted]

Response to Finding No. 703.9

[redacted]

[redacted]

703.10 [redacted]

Response to Finding No. 703.10

[redacted]

[redacted]

703.11 [redacted]

Response to Finding No. 703.11

[redacted]

[redacted]

703.12 [redacted]

Response to Finding No. 703.12

[redacted]

[redacted]

[redacted]

703.13 [redacted]

[redacted]

[redacted]

Response to Finding No. 703.13

[redacted]

[redacted]

704. [redacted]

Response to Finding No. 704

[redacted]

[redacted]

704.1 [redacted]

Response to Finding No. 704.1

[redacted]

[redacted]

[redacted]

704.2 [redacted]

Response to Finding No. 704.2

[redacted]

[redacted]

705. [redacted]

Response to Finding No. 705

[redacted]

[redacted]

705.1 [redacted]

Response to Finding No. 705.1

[redacted]

[redacted]

[redacted]

705.2 [redacted]

Response to Finding No. 705.2

[redacted]

[redacted]

706. Singlera. Singlera is "far, far away" from launching its PanSeer test. (PX7102 (Gao (Singlera) Dep. at 118–19).)

Response to Finding No. 706

This proposed finding is vague, misleading, and against the weight of the evidence. This finding is vague and misleading because Respondents have not defined "far, far away" or what that means. This is a subjective term yet Respondents have cited it as fact.

Further, the proposed finding is misleading and against the weight of the evidence to the extent Respondents imply Singlera is not actively developing its PanSeer MCED test. Singlera has already completed a proof-of-concept study of its PanSeer test in China on 100,000 people, called the Taizhou Longitudinal Study, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the development of the PanSeer MCED test and expects to launch it

as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)).

[redacted]

706.1 Singlera does not plan on marketing its PanSeer test in the US until it has received FDA approval. (Gao (Singlera) Tr. 2873.)

Response to Finding No. 706.1

The proposed finding is misleading and against the weight of the evidence to the extent Respondents imply Singlera is not actively developing its PanSeer MCED test. Singlera has already completed a proof-of-concept study of its PanSeer test in China on 100,000 people, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the

development of the PanSeer MCED test and expects to launch it as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)).

[redacted]

706.2 Singlera is not currently in talks with the FDA. (Gao (Singlera) Tr. 2926–27).

Response to Finding No. 706.2

This proposed finding is incorrect, misleading, and against the weight of the evidence. Dr. Gao clearly testified in the testimony that Respondents cite that Singlera is in discussions with the FDA about its ColonES test. (Gao (Singlera) Tr. 2926–27). The proposed finding is also misleading and vague because it does not explain what it means to be "in talks with the FDA" or its relevance for obtaining FDA approval.

Further, the proposed finding is misleading and against the weight of the evidence to the extent Respondents imply Singlera is not actively developing its PanSeer MCED test. Singlera has already completed a proof-of-concept study of its PanSeer test in China on 100,000 people,

called the Taizhou Longitudinal Study, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the development of the PanSeer MCED test and expects to launch it as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)).

[redacted]

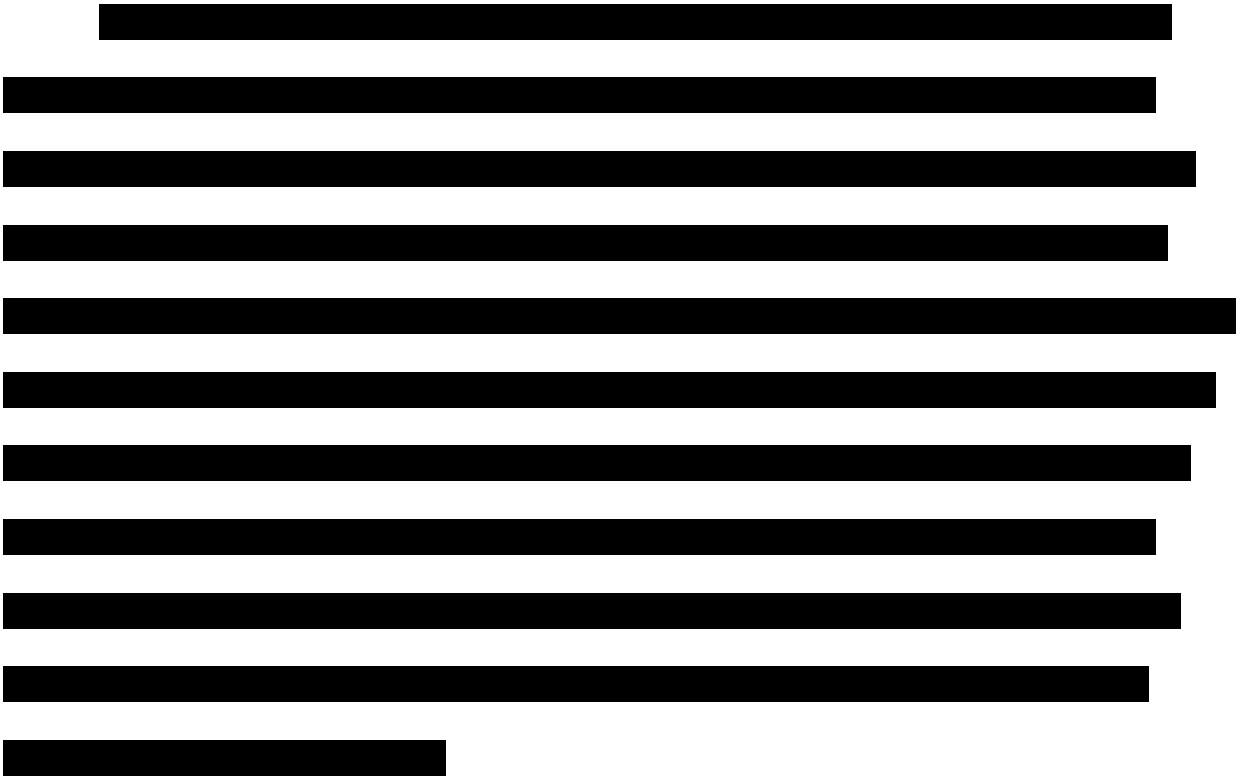
706.3 It will "take at least seven to ten years of time for [the current PanSeer] test to be able to go to FDA". (Gao (Singlera) Tr. 2891).

Response to Finding No. 706.3

The proposed finding is vague, misleading, and against the weight of the evidence. The proposed finding is vague and misleading because Respondents have not explained what it

means to "be able to go to FDA."

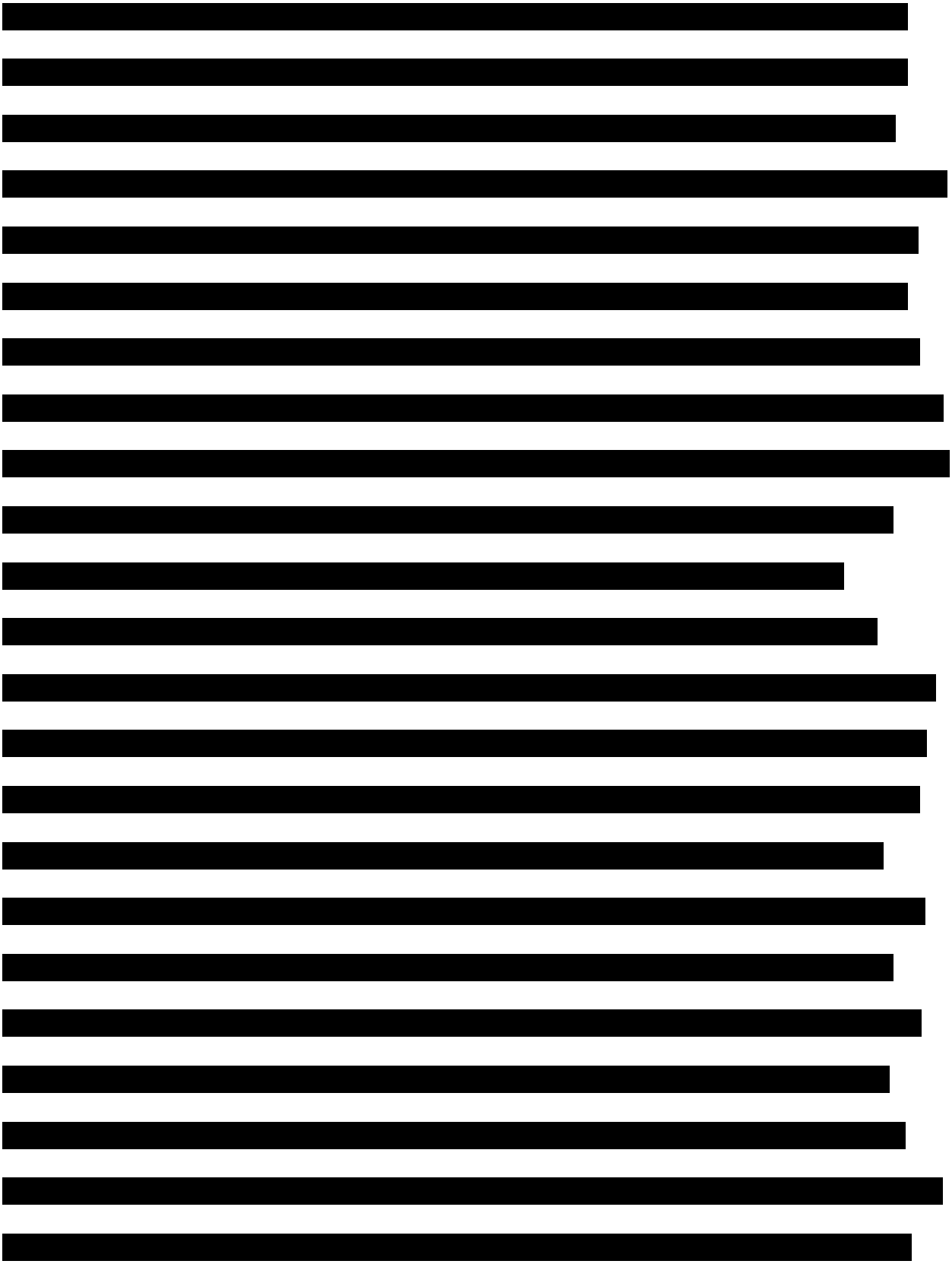
Further, the proposed finding is misleading and against the weight of the evidence to the extent Respondents imply Singlera is not actively developing its PanSeer MCED test. Singlera has already completed a proof-of-concept study of its PanSeer test in China on 100,000 people, called the Taizhou Longitudinal Study, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the development of the PanSeer MCED test and expects to launch it as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)).



707. These far-off projections are consistent with other record evidence regarding the product development timeline to launch an MCED test, and show that many years of development are required before launching an MCED test like Galleri. (PFF ¶¶ 707.1–707.3.)

Response to Finding No. 707

[redacted]



[redacted]

707.1 For each cancer included in an MCED test, you "have to go through a somewhat similar process to what GRAIL did", meaning '"a research phase", '"a test

development phase", and '"a clinical phase", and that must be done "for each cancer", which, if done "serially" would take a "very long time" and is "not practical". (Aravanis (Illumina) Tr. 1895–96.)

Response to Finding No. 707.1

The proposed finding is vague, misleading, unsupported, and against the weight of the evidence. Respondents have merely cited self-serving testimony from their own executive, Illumina's Alex Aravanis, to make a sweeping statement about the development efforts of *all* MCED tests. There is no evidence Dr. Aravanis has the foundation to speak about the development of any MCED test besides potentially Grail's Galleri, let alone every MCED test. The testimony cited involves only a question for Dr. Aravanis about the process for developing Grail's Galleri MCED test and no other test. (Aravanis (Illumina) Tr. 1895–96). Further, Respondents have quoted Dr. Aravanis's testimony as an alleged "fact," despite his lack of foundation and ability to speak to the development of MCED tests. This finding should be wholly disregarded as impermissibly unsupported. Furthermore, the proposed finding is vague and misleading because Respondents have not defined "somewhat similar process," any of the "phases" they reference (i.e. "research phase," "test development," and "clinical"), or "serially." Respondents have also not attempted to quantify how long a process would take beyond a "very long time," which is itself vague and misleading. These appear to be quotes from Dr. Arvanis's cited testimony, which make them mere unsupported testimony about a topic for which he lacks foundation. This is far from a supported "fact" that has any probative value.

Further, the proposed finding is incorrect to the extent Respondents are implying Grail's Galleri can screen for 50 early-stage cancers and is unique compared to other MCED tests.

[redacted]

[redacted]

[redacted]

[redacted]

707.2 As Dr. Chahine of Helio Health confirmed, compared to the R&D process for a single-cancer screening test, "[i]t probably gets exponentially harder if you're adding . . . five and ten cancers, and so just from a practical standpoint, a small company trying to go after multiple cancers at the same time I think is just really just not feasible." (Chahine (Helio) Tr. 1032.)

Response to Finding No. 707.2

The proposed finding is vague, misleading, unsupported, and against the weight of the evidence. The proposed finding is vague and misleading because Respondents have merely stated "[a]s Dr. Chahine of Helio Health confirmed" without explaining what he confirmed. Further, to the extent Respondents are intending to tie this proposed finding to their Proposed Finding ¶ 707.1, this proposed finding is vague and misleading because Dr. Chahine clearly prefaced his comments by saying "it *probably* gets exponentially harder" and "a *small* company trying to go after multiple cancers at the same time." (Chahine (Helio) Tr. 1032). As explained in the response to Respondent's Proposed Finding ¶ 707.1, this proposed finding does not provide sufficient support for the sweeping conclusion Respondents intend to make about *all* MCED test developers. (*See* Response to RPFF ¶ 707.1).

Further, the proposed finding is incorrect to the extent Respondents are implying Grail's Galleri can screen for 50 early-stage cancers and is unique compared to other MCED tests.

[redacted]

[redacted]

[redacted]

[redacted]

707.3 Accounting for all of these steps in the development process, Dr. Cote opined that most of the putative MCED developers identified by Complaint Counsel were at least five to seven years away from launching any kind of MCED test. ([redacted] 3727, [redacted]

Response to Finding No. 707.3

[redacted]

- [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

708. No proof of interchangeability. Even if the tests in development were on the market, or could be expected to launch in the near term, Complaint Counsel failed to prove that any of these tests will be reasonably interchangeable with Galleri if and when they are launched. (PFF ¶¶ 708.1–708.3.)

Response to Finding No. 708

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). [redacted]

The proposed finding should also be disregarded because it is vague, misleading, unsupported, against the weight of the evidence, and unreliable. The proposed finding is unsupported because Respondents have provided only cross-references to their own findings in support of this legal conclusion, none of which are reliable evidence to support the finding. (*See* Response to RPFF ¶¶ 708.1, 708.2, 708.3). The proposed finding is also vague and misleading

because they have used legal terminology like "reasonably interchangeable" without defining it or offering any explanation of what it means. [redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

708.1 The purchasers of any MCED test will be patients, health care providers and/or insurers. (*See* RX3871 (Willig Expert Report) ¶ 12.)

Response to Finding No. 708.1

The proposed finding should be disregarded because it is impermissibly unsupported and unreliable. Respondents have only cited to their own expert report from Dr. Robert Willing in direct contravention of the Court's order barring the use of expert testimony "to support factual propositions that should be established by fact witnesses or documents," (*see* Order on Post-Trial Briefing at 3), and thus this finding should be wholly disregarded as unsupported and unreliable.

708.2 Complaint Counsel did not call any medical expert, nor a single patient, health care provider or insurer to testify that he/she would substitute one of the tests in development (were it ever to be sold) for Galleri. (RX6004 (Katz Trial Dep. at 18.)

Response to Finding No. 708.2

[redacted]

[redacted]

708.3 Nor did Complaint Counsel conduct any surveys of such groups. (RX6004 (Katz Dep. at 19–20) (Complaint Counsel's expert "didn't attempt to fill those

information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior.").)

Response to Finding No. 708.3

[redacted]

709. Ample proof of no interchangeability. Numerous witnesses testified that Galleri is not reasonably interchangeable with the MCED tests in development. (PFF ¶¶ 709.1–709.6.)

Response to Finding No. 709

The proposed finding is unsupported by any reliable evidence and is against the

overwhelming weight of the evidence. [redacted] Instead, the overwhelming weight of the evidence shows that Galleri is reasonably interchangeable with MCED tests in development. [redacted]

Therefore, this Court should disregard the proposed finding.

> 709.1 Francis deSouza, Illumina's CEO, testified, based on his conversations with doctors during due diligence for the Transaction, that Galleri would not compete with tests that screen for fewer than ten cancers or with tests that do not identify cancer signal of origin. (deSouza (Illumina) Tr. 2336–37 ("[D]octors who are looking for 50 cancers and doing a screen would not want a test that did not tell the patient where that cancer was. They felt that that [it] would [not work] to raise so much anxiety in a person without telling them what they actually have. And so for that use case, for doing screening of a healthy person to identify if they have 50 cancers, they felt it was essential that as part of the conversation with the patient you're immediately able to say what to do next, you know, look at this organ, image your pancreas or something . . . and so they would not substitute Galleri with another test that identified 50 cancers but didn't tell you what cancer it was and where it was, and so they are not substitutes."))

Response to Finding No. 709.1

The proposed finding should be wholly disregarded as unreliable hearsay. Respondents have offered the self-serving testimony of Illumina's CEO, Francis deSouza, who has merely repeated what he allegedly heard from unnamed "doctors." Even if you were to accept the premise that Mr. deSouza in fact heard from a single doctor, let alone enough sufficient to make

this sweeping statement about *all* doctors' preferences, Respondents have now tried to offer what he allegedly heard for the truth of the matter asserted—a violation of the rule against hearsay. Neither Respondents nor Mr. deSouza have provided any information about the doctors he allegedly spoke with or their qualifications for making the comments they made. Even more, Respondents have offered this hearsay as the sole support to establish a seemingly legal conclusion about competition in the MCED market. This proposed finding should be disregarded as unsupported and unreliable.

Respondents also offer this hearsay while ignoring the ample evidence on the record about competition in the MCED market. [redacted]

Further, the proposed finding is incorrect as it relies upon testimony from Mr. deSouza that presupposes Grail's Galleri can screen for 50 early-stage cancers. [redacted]

[redacted]

[redacted]

709.2 Illumina's Chief Technology Officer (and GRAIL's former Chief Science Officer and Head of R&D), Dr. Alex Aravanis, testified that it is "unlikely" Galleri will

> compete with a test that screens for fewer than ten cancers and that Galleri would not compete with a test that does not identify cancer signal of origin, since it would be used in a very different clinical context than Galleri. (Aravanis (Illumina) Tr. 1921–22.)

Response to Finding No. 709.2

The proposed finding should be disregarded as unsupported, unreliable, vague, misleading, and against the weight of the evidence. Respondents have merely cited self-serving testimony from their own executive, Illumina's Alex Aravanis, to make a sweeping statement about competition between MCED tests. There is no evidence Dr. Aravanis has the foundation to speak about competition between MCED tests as an Illumina executive, regardless of his prior experience at Grail. Respondents also made no attempt to lay a foundation for how or why Dr. Aravanis would know whether Grail's Galleri will "compete with a test that screens for fewer than ten cancers and that Galleri would not compete with a test that does not identify cancer signal of origin." Further, with respect to his testimony about the cancer signal of origin, Dr. Aravanis's testimony merely said he did not "believe so" when asked about competition with the Galleri. The proposed finding is also vague, misleading, and unsupported because Respondents have not defined or identified the term "clinical context" as used in the finding. To the extent they are referring to the setting that a physician would give an MCED test, Dr. Aravanis clearly lacks the foundation to speak about the practicing behavior of all physicians.

Respondents also offer this unreliable testimony while ignoring the ample evidence on the record about competition in the MCED market. [redacted]

Further, the proposed finding is incorrect as it relies upon testimony from Dr. Aravanis that presupposes Grail's Galleri can detect 50 cancers. [redacted]

[redacted]

[redacted]

709.3 GRAIL's then-CEO, Hans Bishop, testified that he did not foresee Galleri competing with other MCED developers, such as Guardant, Freenome, Exact/Thrive and Singlera, given the substantial differences between the tests those companies may be developing and Galleri. (Bishop (GRAIL) Tr. 1390–91; 1393–94 (Freenome); 1397 (Exact/Thrive); 1399 (Singlera).)

Response to Finding No. 709.3

The proposed finding should be disregarded as misleading, unsupported, unreliable, and against the weight of the evidence. Respondents have cited the self-serving testimony of Grail's former CEO, Hans Bishop, whose testimony does not even support Respondents' proposed finding. With respect to Guardant and Freenome, Mr. Bishop was testifying about competition between the companies' *single-cancer* screening tests and Grail's Galleri MCED test. (*See* Bishop (Grail) Tr. 1390-91 (testifying that he was only referring to Guardant's "single cancer focused test" and "the reason that we should not use Galleri instead of any of those single tests is because those single tests are optimized for detecting those single cancers"); 1393-94 (testifying that he does not think Freenome's single-cancer colorectal test will compete with Grail's Galleri "[f]or the same reasons we've covered, that [single-cancer tests] should be used in combination"). Complaint Counsel does not disagree that Grail's Galleri does not compete with single-cancer screening tests. [redacted]

With respect to Thrive/Exact and Singlera, Mr. Bishop testified that he *did not know* if their MCED tests would compete with Grail's Galleri. (Bishop (Grail) Tr. 1397 (in response to a question about whether he expected "Exact's test in development to compete with Galleri if it ever becomes available for purchase," testifying that "[t]hat's really not possible to understand at this point in time because we don't know what the performance features of such a test may be"); 1399 (replying to a question about competition with Singlera's PanSeer MCED test that "[a]gain, I – I don't know . . . I don't think it's possible to know"). This proposed finding should thus be completely disregarded as misleading, unsupported, and unreliable.

Even if supported, this proposed finding is entirely against the evidence including even contradictory testimony from Mr. Bishop. Mr. Bishop also testified that patients benefit from having multiple MCED tests in development, explaining: "difficult problems are, by definition, hard to solve, and having a multitude of different approaches is a good thing." (PX7069 (Bishop (Grail) IHT at 154-56)). He went on to emphasize that "one of the exciting things about the horizon scanning we do and the field in general is the number of different approaches different companies are taking." (PX7069 (Bishop (Grail) IHT at 154-56). Whereas Grail has chosen to focus on cfDNA methylation, he explained that other companies have chosen to focus on protein analysis and others on multi-omics that "combin[e] those different modalities." (PX7069 (Bishop (Grail) IHT at 154-56)). These approaches, Bishop emphasized, all intend to reach the same goal—"to get to the highest-performing technology." (PX7069 (Bishop (Grail) IHT at 154-56)). [redacted]

[redacted] The proposed finding should thus be wholly disregarded as unsupported, unreliable, and against the weight of the evidence.

709.4 Dr. Josh Ofman, GRAIL's Chief Medical Officer, testified that Galleri will not compete with MCED tests that are first pursuing colon cancer tests: "[w]e screen for colon cancer with stool-based colon cancer screening tests or colonoscopy, which is the gold standard, and so . . . for people who want to use blood to look for colon cancer, they'll just do that. But adding a multicancer early detection test to the single-cancer screening test is a very different activity. They're not really competing." (Ofman (GRAIL) Tr. 3310–11.) Dr. Ofman also testified that Galleri would not compete with a test that detected two or three cancers, because "conceptually what you're trying to do with Galleri is very different than something you'd be trying to do with a test that says we can find stomach and esophageal cancer." (Ofman (GRAIL) Tr. 3312–13.)

Response to Finding No. 709.4

[redacted]

[redacted]

709.5 Dr. Cote testified that [redacted]

Response to Finding No. 709.5

[redacted]

[redacted]

[redacted]

[redacted]

709.6 [redacted]

Response to Finding No. 709.6

[redacted]

[redacted]

[redacted]

710. The intuition as to complementarity between a 50 cancer test and a test that screens for fewer cancers was also supported by some of Complaint Counsel's third party witnesses. (PFF ¶¶ 710.1–710.3.)

Response to Finding No. 710

The proposed finding is incorrect to the extent Respondents are implying Grail's Galleri can provide early detection of 50 cancers. [redacted]

[redacted]

[redacted]

Furthermore, the proposed finding is vague, misleading, and unsupported because Respondents have not explained or defined the phrase "intuition as to complementarity." This proposed finding, and use of the word "complementarity, appears to be a legal argument proposed as a "fact" in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. §

3.46; Order on Post-Trial Findings). Therefore, this Court should disregard the proposed finding.

710.1 [redacted]

Response to Finding No. 710.1

[redacted]

[redacted]

710.2 [redacted]

Response to Finding No. 710.2

[redacted]

[redacted]

710.3 In response to questioning about what customers will view PanSeer and Galleri as substitutable options, Singlera's Chairman Gary Gao testified that "I don't think there is a product yet. And I could not say how we are interchangeable right now . . .." (PX7042 (Gao (Singlera) IHT at 101).)

Response to Finding No. 710.3

The proposed finding is misleading, incorrect, unreliable, and against the weight of the evidence to the extent Respondents are implying that Singlera's PanSeer MCED test does not compete with Grail's Galleri. [redacted]

Further, the proposed finding is misleading and against the weight of the evidence to the extent Respondents imply Singlera is not actively pursuing the commercialization of its PanSeer

MCED test. Singlera has already completed a proof-of-concept study of its PanSeer test in China on 100,000 people, known as the Taizhou Longitudinal Study, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the development of the PanSeer MCED test and expects to launch it as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)). Therefore, this Court should disregard the proposed finding.

711. Complaint Counsel has no testimony from potential consumers of MCED tests. (*See* RX6004 (Katz Trial Dep. at 18.)

Response to Finding No. 711

This proposed finding is misleading to the extent it implies that Complaint Counsel has failed to show a substantial lessening of competition. [redacted] Therefore, this Court should disregard the proposed finding.

712. The only testimony that Complaint Counsel elicited regarding this point is self-serving testimony from certain MCED test developers that they view GRAIL as a rival and expect the tests they are working on to compete with Galleri (if ever they were launched). (*E.g.*, [redacted]; PX7100 (Chudova (Guardant) Dep. at 22–23); PX7042 (Gao (Singlera) IHT at 96, 98–100); [redacted]

[redacted]
PX7068 (Perettie, IHT at 76).)

Response to Finding No. 712

[redacted]

3. ***Brown Shoe* Factors**

a. No industry or public recognition of the alleged market as a separate economic entity

713. Neither the industry nor the public recognizes an MCED market as defined by Complaint Counsel. (PFF ¶¶ 717–721.)

Response to Finding No. 713

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely represented their

argument as a "fact." The proposed finding is also vague and ambiguous because it refers to an industry view without identifying any industry. The proposed finding is also unsupported because no evidence is cited for the factual proposition.

714. There is an NGS-based multi-cancer early detection test available for sale in the U.S. (Galleri) and a number of companies are working to develop cancer screening tests, some of which have been loosely described as MCED tests. (PFF ¶¶ 698, 701–706.)

Response to Finding No. 714

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely represented their argument as a "fact." The proposed finding is also vague and ambiguous because it refers to how "some" tests are described without identifying which tests it refers to. The proposed finding is also unsupported because no evidence is cited for the factual proposition.

715. But there is no industry or public recognition of a separate "economic entity" comprised of any NGS-based screening test that detects more than one cancer type. (PFF ¶¶ 717–721.)

Response to Finding No. 715

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely represented their argument as a "fact." The proposed finding is also vague and ambiguous because it refers to an industry view without identifying any industry. The proposed finding is also unsupported because no evidence is cited for the factual proposition.

715.1 Galleri is the only test on the market, and it has been shown (with published data) to detect more than 50 cancers and tissue of origin. (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100.)

Response to Finding No. 715.1

The proposed finding should be disregarded because it is incorrect, unreliable, and against the weight of the evidence. [redacted]

[redacted]

[redacted]

715.2 None of the MCED tests in development has had a single sale. (*See* Bishop (GRAIL) Tr. 1401.)

Response to Finding No. 715.2

The proposed finding is misleading and against the weight of the evidence to the extent Respondents are implying that Grail is significantly ahead of other MCED developers in the commercialization of an MCED test. [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

715.3 None has been shown to detect more than 10 cancers (and most far fewer) and none has the ability to detect cancer signal of origin. (PFF ¶¶ 684.1–684.2.)

Response to Finding No. 715.3

The proposed finding is vague, misleading, and against the weight of the evidence. The proposed finding is vague and misleading because Respondents have not identified or defined their reference to "none" in their proposed finding. To the extent Respondents are referring to MCED tests other than Grail's Galleri, the proposed finding is misleading, against the weight of the evidence, and incorrect to the extent they are drawing a comparison to Grail's Galleri and its ability. [redacted]

The proposed finding is incorrect to the extent Respondents are implying Grail's Galleri can provide early detection of 50 cancers. [redacted]

[redacted]

[redacted]

715.4 Indeed, most of the in-development tests are focused at present solely on detecting a single cancer with the aspiration of one day detecting more cancers by adding additional bio markers and conducting additional clinical trials. (*See* Chudova (Guardant) Tr. 1154, 1179; [redacted]

Response to Finding No. 715.4

[redacted]

[redacted]

716. The available industry or public information about the putative MCED tests in development does not suggest that these tests belong in the same product market as Galleri. Instead, they make clear that they are all very different from Galleri. (PFF ¶¶ 717–721.)

Response to Finding No. 716

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16

C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely represented their argument as a "fact." The proposed finding is also vague and ambiguous because it refers to an industry view without identifying any industry. The proposed finding is also unsupported because no evidence is cited for the factual proposition.

717. Analyst reports from investment banks that cover the broader biotechnology space recognize that Galleri is very different. (PFF ¶¶ 717.1–717.2.)

Response to Finding No. 717

The proposed finding should be disregarded as incorrect and unreliable. Respondents only cite to their own proposed findings to support an overarching claim that "investment banks that cover the broader biotechnology space recognize that [the] Galleri is very different," each underlying finding, as explained below, is entirely reliant an unreliable, vague evidence and hearsay. (*See* Response to RPFF ¶¶ 717.1, 717.1.1, 717.1.2, 717.1.3, 717.2, 717.2.1). The proposed finding is thus unreliable. Further, the proposed finding is misleading and unreliable because Respondents have not defined or explained "investment banks," the "broader biotechnology space," or what it means that Grail's Galleri is "very different." Respondents have also not explained the foundation for "investment banks that cover the broader biotechnology space" to compare Grail's Galleri to other tests, let alone to distinguish the Galleri from other MCED tests. The proposed finding is further misleading because Respondents haven't compared Grail's Galleri to other MCED tests—instead, Respondents have merely stated that these banks recognize that "Galleri is very different" without actually explaining finishing the comparison to another test. The proposed finding is thus incomplete and unreliable because Respondents haven't even finished their own comparison.

The proposed finding is also against the weight of the evidence to the extent Respondents are implying that Grail's Galleri does not compete with other MCED tests. [redacted]

[redacted]

717.1 For instance, a report on the liquid biopsy market from Cowen notes that GRAIL has "conducted systematic clinical studies" and that Galleri "has been shown to be capable of identifying >50 types of cancers by scanning methylation patterns". (PX2022 (Cowen) at 27).)

Response to Finding No. 717.1

The proposed finding should be disregarded as unreliable and incorrect to the extent Respondents are implying that Grail's Galleri has been clinically shown to be capable of providing early detection of 50 cancers in asymptomatic patients. The proposed finding is unreliable because Respondents are relying on statements made in a third-party document from a party that was neither called as a witness nor otherwise provided evidence to indicate the reliability of the claim. As an out-of-court statement offered for the truth of the matter asserted, the proposed finding is hearsay to the extent Respondents are implying that Grail's Galleri can detect 50 cancers early in a screening setting.

[redacted]

[redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]}

717.1.1 The only other entity it recognizes as pursuing a multicancer screening test is Thrive, but notes that it had only been shown to detect 10 cancers and required the use of a confirmatory PET-CT scan. (PX2022 (Cowen) at 27, 29.)

Response to Finding No. 717.1.1

The proposed finding should be discarded because it is impermissibly vague, misleading, unreliable, and against the weight of the evidence. The proposed finding is vague and misleading because Respondents have not attributed the alleged fact to anyone, instead merely

say "[t]he only other entity *it* recognizes" without specifying who or what they are referencing. The proposed finding is also unreliable to the extent they are referring to the report from Cowen Research referenced in their citation and implying that Thrive can only "detect 10 cancers" and requires "the use of a confirmatory PET-CT scan." Respondents are relying on statements made in a third-party document from a party that was neither called as a witness nor otherwise provided evidence to indicate the reliability of the claims. As an out-of-court statement offered for the truth of the matter asserted, the proposed finding is hearsay to the extent Respondents offer the Cowen Report to suggest anything about the functionality of Thrive's CancerSEEK test.

The proposed finding is also against the weight of the evidence to the extent Respondents are implying that Thrive/Exact's CancerSEEK can detect fewer cancers than Grail's Galleri.

[redacted]

717.1.2 The report notes that Freenome and Guardant are among the companies in a separate market segment pursuing single-cancer screening tests to detect colorectal cancer (PX2022 (Cowen) at 30–31), lists Singlera in passing under the heading "[s]ome [o]thers" following its summary of the colorectal cancer screening market (PX2022 (Cowen) at 33), and considers Helio in a separate segment for "High Risk Cancer Detection" for its liver cancer screening test. (PX2022 (Cowen) at 29, 35, 37, 38.)

Response to Finding No. 717.1.2

The proposed finding should be discarded because it is impermissibly vague, misleading, unreliable, and against the weight of the evidence. The proposed finding is vague and misleading because Respondents have stated "[t]he report" without providing any additional

context for what report they're referencing. The proposed finding is also unreliable to the extent they are referring to the report from Cowen Research used in their citation. The proposed finding is unreliable because Respondents are relying on statements made in a third-party document from a party that was neither called as a witness nor otherwise provided evidence to indicate the reliability of their claim. As an out-of-court statement offered for the truth of the matter asserted, the proposed finding is hearsay to the extent Respondents are implying that Freenome and Guardant are "in a separate market segment pursuing single-cancer screening tests to detect colorectal cancer" and Helio is in a separate market segment for "liver cancer screening tests" only. [redacted]

[redacted]

717.1.3 Cowen does not recognize [redacted] as pursuing early cancer detection at all: it notes [redacted] as a participant in the recurrence monitoring/MRD and "liquid biopsy for biopharma" (*i.e.* companion diagnostic) segments (PX2022 (Cowen) at 46–53), and [redacted] in the therapy selection and "liquid biopsy for biopharma" market segments (PX2022 (Cowen) at 39, 54).

Response to Finding No. 717.1.3

[redacted]

[redacted]

[redacted]

717.2 An analyst note from SVBLeerink comes to a similar conclusion, only mentioning GRAIL and Thrive as pursuing "multi-cancer detection" and noting that Guardant and Freenome are among those in the colorectal cancer screening space. (PX4180 (SVBLeerink) at 32.)

Response to Finding No. 717.2

[redacted]

[redacted]

[redacted]

717.2.1 SVBLeerink also notes a number of "must have" features for an multi-cancer screening assay, including cancer signal of origin capability (which it notes as "essential"); "99%+ specificity"; detection of "higher mortality cancers with no current screening methodologies"; "and [l]arge-scale, prospective trials that reflect prevalence of cancer in the real world". (PX4180 (SVBLeerink) at 32.) Only Galleri can claim to have these features. (PFF ¶¶ 61–62, 355, 400–01.)

Response to Finding No. 717.2.1

The proposed finding is vague, misleading, unsupported, unreliable, incorrect, and against the weight of the evidence. The proposed finding is vague and misleading to the extent Respondents are alleging the "must have" features they list are in fact required features of an MCED test. Respondents have not provided any explanation for the reliability or credibility of SVBLeerink, including its ability to identify required features of an MCED test. Respondents have also not identified what it means to be a "must have" feature or its relationship to competition in the market for MCED tests. The proposed finding is also unreliable because Respondents are relying on statements made in a third-party document from a party that was neither called as a witness nor otherwise provided evidence to indicate the reliability of their claim. As an out-of-court statement offered for the truth of the matter asserted, the proposed finding is hearsay to the extent Respondents are implying that the features they list are "must have" features for an MCED test.

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

The proposed finding is also incorrect to the extent Respondents are implying that Grail has conducted multiple prospective clinical trials on its Galleri test "that reflect prevalence of cancer in the real world." Grail had released results from two clinical studies as of trial: the Circulating Cell-free Genome Atlas ("CCGA") study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). [redacted] Grail's PATHFINDER study was an interventional study that involved 6,600 patients. (Ofman (Grail) Tr. 3293). Grail has only produced interim results from its PATHFINDER study, which do not show the Galleri can detect 50 cancers in an asymptomatic screening population. (Cote Tr. 4000-02; Ofman (Grail) Tr. 3293, 3298). According to Dr. Ofman, to find 50 cancer types "in a real-world population is going to require hundreds of thousands of people [and] PATHFINDER was not designed to do that." (Ofman (Grail) Tr. 3298). [redacted] The proposed finding is incorrect to the extent Respondents are implying that these trial results are considered "[l]arge-scale, prospective trials that reflect prevalence of cancer in the real world."

The proposed finding is also incorrect and misleading to the extent Respondents are implying that Grail's Galleri has "99%+ specificity" in its intended use for an asymptomatic cancer screening population for an FDA approved test. [redacted]

[redacted] Without an FDA-approved clinical trial, the proposed finding is misleading and incorrect to the extent Respondents are claiming Grail's Galleri has a "99%+ specificity." Therefore, this Court should disregard the proposed finding.

718. [redacted]

Response to Finding No. 718

[redacted]

[redacted]

718.1 [redacted]

[redacted]

[redacted]

Response to Finding No. 718.1

[redacted]

[redacted]

[redacted]

719. The features and functions of Galleri are described in detail in several peer-reviewed publications, including Annals of Oncology, (RX3409 (Klein et al 2021); RX3430 (Liu et al 2020)), and GRAIL has multiple clinical trials listed at clinicialtrials.gov. (*See* RX3133 (Clinicaltrials.gov); RX3134 (Clinicaltrials.gov); RX3135 (Clinicaltrials.gov).)

Response to Finding No. 719

Complaint Counsel has no specific response to the proposed finding. To the extent Respondents intend to offer the content of any of the cited materials for the truth of the matter asserted in the article, Complaint Counsel objects to the evidence as hearsay that should be wholly disregarded. These articles are out-of-court statements that Respondents do not submit with sufficient indicia of reliability for admission as evidence.

719.1 The available peer-reviewed publications show, with only two exceptions, that Complaint Counsel's so-called "MCED" developers have only published peer reviewed articles or initiated clinical trials, if any, for single-cancer screening tests. (RX3132 (Clinicaltrials.gov); RX3426 (Lin et al., 2021), RX3592 (Putcha et al., 2020); RX3740 (Westesson et al., 2020); RX3128 (Clinicaltrials.gov), RX3405 (Kim et al., 2019) (Guardant); RX3616 (Roy et al., 2019); RX3617 (Roy et al., 2019) (Helio).)

Response to Finding No. 719.1

The proposed finding is vague, misleading, confusing, incomplete, unsupported, incorrect, and against the weight of the evidence. The proposed finding is vague, misleading, confusing, and incomplete because Respondents have claimed that "with only two exceptions" but not identified what those exceptions entail. Further, the proposed finding is unsupported and incomplete because Respondents have merely cited a collection of third-party documents that Respondents appear to suggest provides an exhaustive list of resources to show peer-reviewed publications. Respondents had the opportunity to collect evidence, including documents and testimony, from each of the MCED developers yet still only supported the finding with citations

to third-party materials. These citations do not and cannot support an assertion about the universe of all "available peer reviewed publications" as Respondents allege. As an unsupported "fact," the proposed finding is thus unreliable and should be disregarded.

[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

720. Some have not even published articles or initiated clinical trials relating to cancer screening at all. (RX3869 (Cote Expert Report) at 301 (FMI/Roche); RX3869 (Cote Expert Report) ¶ 228, at 303 (Natera).)

Response to Finding No. 720

The proposed finding should be disregarded because it is vague, misleading, and incorrect. The proposed finding is vague and misleading because Respondents have not defined or explained "some" or "published articles." The definition of these words is material for understanding the proposed finding, and without defining either the proposed finding is unsupported and thus unreliable. [redacted]

721. Other than Galleri, only Exact/Thrive and Singlera have conducted clinical trials and/or published one or more peer reviewed articles about MCED tests in development. (RX3419 (Lennon et al., 2020); RX3115 (Chen et al., 2020).) But that data shows that these tests are very different from Galleri. (PFF ¶¶ 721.1–721.4.)

Response to Finding No. 721

[redacted]

[redacted]

[redacted]

721.1 The Exact/Thrive data shows only that its CancerSEEK assay can detect, at most, 10 types of cancer—with no identification of tissue of origin (a whole body PET-CT scan is required to identify the tissue of origin for every positive case). (RX3419 (Lennon et al 2020); Cote Tr. 3811–14.)

Response to Finding No. 721.1

[redacted]

[redacted]

[redacted]

721.2 [redacted]

Response to Finding No. 721.2

[redacted]

[redacted]

[redacted]

721.3 Similarly, the published Singlera data is from a 418–sample case control study and shows only that Singlera's PanSeer assay could detect five types of cancer. (RX3115 (Chen et al 2020) at 3.)

Response to Finding No. 721.3

The proposed finding is misleading to the extent it implies that Singlera's PanSeer assay can only detect five types of cancer. Rather the weight of the evidence shows that the PanSeer test is designed to work for any type of cancer. (PX7102 (Gao (Singlera) Dep. at 94-95)). As Dr. Gao testified that Singlera's "goal is pan-cancer" for the PanSeer test. (Gao (Singlera) Tr. 2881). Therefore, this Court should disregard the proposed finding.

721.4 Moreover, the data show that PanSeer achieved only 96.1% specificity, (RX3115 (Chen et al 2020) at 1), [redacted]

Response to Finding No. 721.4

[redacted]

[redacted]

[redacted]

[redacted]

b. The products' peculiar characteristics and uses

722. Unique characteristics. Galleri sequences a patient's blood sample to detect methylation and then takes the data and analyzes it using a machine learning algorithm, which will classify the methylation pattern as a cancer signal or noncancer signal. (Ofman (GRAIL) Tr. 3285–88; Aravanis (Illumina) Tr. 1886–87; RX3025 (Alexander et al 2021) at 4.)

Response to Finding No. 722

The proposed finding is vague and misleading to the extent Respondents are implying that Grail's Galleri is the only MCED test to use blood samples or a machine learning algorithm. The evidence makes clear that other MCED tests use blood draws and machine learning algorithms. (*See* CCFF ¶¶ 1904-2594).

723. If a cancer signal is detected, the sample is analyzed again using the machine learning algorithm to predict the cancer's signal of origin. (Ofman (GRAIL) Tr. 3285–88; Aravanis (Illumina) Tr. 1886–87; RX3025 (Alexander et al 2021) at 4.)

Response to Finding No. 723

The proposed finding is misleading and against the weight of the evidence to the extent Respondents are implying that Grail's Galleri test will not require additional scanning to determine the tissue of origin after a positive result. The weight of the evidence shows that Grail's MCED will require additional screening to identify the tissue of origin, including as its former CEO, Hans Bishop, testified a body scan for certain patients. (CCFF ¶ 3565; *see also*

CCFF ¶¶ 3566-69). Therefore, this Court should disregard the proposed finding.

724. Galleri has been shown to detect more than 50 cancers with high specificity, and cancer signal of origin with high accuracy. (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100.) No other test has been shown to detect more than 10 cancers or been able to detect the cancer signal of origin. (*See* PFF ¶¶ 684.1–684.2.)

Response to Finding No. 724

The proposed finding is incorrect and against the weight of the evidence. To the extent Respondents are implying that Grail's Galleri can identify the tissue of origin without additional screening, the proposed finding is against the weight of the evidence. The weight of the evidence shows that Grail's MCED will require additional screening to identify the tissue of origin, including as its former CEO, Hans Bishop, testified a body scan for certain patients. (CCFF ¶ 3565; *see also* CCFF ¶¶ 3566-69).

[redacted]

[redacted]

[redacted]

[redacted]

725. Most of the tests in development are too underdeveloped to permit a meaningful comparison of their features, and at present are being actively developed as single cancer tests (not MCED tests), but the three for which there are data are readily distinguishable, as illustrated in the below table:

Table 7

Test	Galleri	CancerSEEK			PanSeer
		1 Blood Test	2 Blood Tests	2 Blood + PET-CT	
Study	CCGA3	DETECT-A			Taizhou L.S.
Types of Cancer	50	10			5
Cancer Signal of Origin	Yes	No	No	Yes	No
Specificity	99.5%	95.3%	98.9%	99.6%	96.1%
Sensitivity	51.5%	30.2%	27.1%	15.6%	94.9%
PPV	44.4%	5.9%	19.4%	28.3%	

(RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4.)

Response to Finding No. 725

The proposed finding is unsupported, misleading, improper, against the weight of the evidence. The statement "[m]ost of the tests in development are too underdeveloped to permit a meaningful comparison of their features" is an argument, not a fact, and is unsupported by the sources cited supports that statement. This Court should disregard that statement as unsupported.

The proposed finding is misleading because the overwhelming weight of the evidence shows that the CCGA study is not indicative of Galleri's performance in the intended use (asymptomatic) population as explained below. Any attempt to compare directly the results in DETECT-A (an interventional study involving asymptomatic individuals) and Taizhou (an observational study involving asymptomatic individuals) with CCGA (a case-control study involving diagnosed cancer patients, including patients with Stage IV cancer) meaningless and inherently unreliable. They are fundamentally different types of studies. Dr. Ofman of Grail conceded that "[t]o find all 50 cancer types in a real-world population would require hundreds of thousands of people[.]" (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298).

[redacted]

The authors of the CCGA-3 sub-study itself make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Accordingly, Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (i.e. in an asymptomatic screening population).

To put the above points plainly, a case control study will tend to produce inflated performance results relative to how a test would performance in an asymptomatic screening population (the actual population in which MCED tests are intended to be used). Notwithstanding this, and notwithstanding the above admissions, Respondents nonetheless attempt to compare their case-control results to results from studies involving asymptomatic populations and pretend as if they are comparing apples to apples. They are not; the attempt itself is inherently misleading.

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See, e.g.*, RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.*, CCFF ¶ 6233). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has never demonstrated its Galleri MCED test can reliably detect 50 cancer types in an asymptomatic patient. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of

trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population–a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394 (Appendix B: Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

The proposed finding is also incomplete and misleading to the extent it suggests that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population. [redacted]

[redacted]

726. In addition to obvious differences in the number of cancers detected, the nature of the testing and the ability to detect cancer signal of origin, there are significant differences between the specificity and sensitivity of the tests. (PFF ¶¶ 726.1–726.8.)

Response to Finding No. 726

[redacted]

[redacted]

726.1 For example, the specificity of Galleri is 99.5% compared to 95.3% for the single blood draw in CancerSEEK (the apples-to-apples comparison). While those numbers may seem close, the difference between them is huge in the context of a screening test. (*See* RX3869 (Cote Expert Report) ¶ 93.)

Response to Finding No. 726.1

[redacted]

[redacted]

[redacted]

[redacted]

726.2 The 4.2% difference means that for every 100,000 patients screened, an additional 4,200 people using CancerSEEK will receive a false positive result that they have cancer. (*See also* Cote Tr. 3779–81.)

Response to Finding No. 726.2

[redacted]

[redacted]

[redacted]

[redacted]

726.3 The specificity of CancerSEEK comes closer to Galleri only when an additional blood draw and full body PET-CT scan are added.

Response to Finding No. 726.3

[redacted]

[redacted]

726.4 The sensitivity of the tests is not at all comparable (51.5% as compared to 30.2%). (*See* RX3409 (Klein 2021) at 5; RX3419 (Lennon et al., 2020) at 7.) This means that when both tests are used in a random population, CancerSEEK will miss 20% more instances of cancer in patients than Galleri would. (*See* Cote Tr. 3778-79.)

Response to Finding No. 726.4

[redacted]

[redacted]

[redacted]

[redacted]

726.5 These metrics enable a calculation of positive predictive value ("PPV"): the percentage of participants with a positive test result who truly have the disease. (PX0043 (GRAIL) at 93; *see also* PX7103 (Jamshidi (GRAIL) Dep. at 136-37).)

Response to Finding No. 726.5

[redacted]

[redacted]

726.6 Any analysis of CancerSEEK's characteristics is premature, as Exact is going back to the drawing board with the test and "combining the Exact Sciences and Thrive approaches in one test." (RX4007 (Exact/Thrive) at 7.)

Response to Finding No. 726.6

[redacted]

[redacted]

726.7 [redacted]

Response to Finding No. 726.7

[redacted]

726.8 [redacted]

Response to Finding No. 726.8

[redacted]

727. Different uses. The Galleri test is recommended for use in asymptomatic adults aged 50 and older. (PX0043 (GRAIL) at 5.) It is intended to be used in addition to, and not to replace, other cancer screening tests. (Ofman (GRAIL) Tr. 3309–10.)

Response to Finding No. 727

The proposed finding is misleading to the extent it implies that Galleri's competitive have different customers. [redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

728. While we do not know exactly what the MCED tests in development will look like, if ever they launch, there is no question that the tests Complaint Counsel points to will be used very differently than Galleri. (PFF ¶¶ 728.1–**Error! Reference source not found.**.)

Response to Finding No. 728

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). This proposed finding is also incorrect in stating that there is "no question" that other tests will be used "differently than Galleri." Complaint Counsel absolutely contests this point and directs this Court to its Post-Trial Brief at Section II.B. and its Post-Trial Reply Brief at Section III.B.

The proposed finding is also vague and ambiguous because it claims that tests "will be used very differently" without any explanation. The proposed finding is also unsupported because no evidence is cited for the factual proposition. Therefore, this Court should disregard the proposed finding.

728.1 Most of the tests are single cancer tests to which the developer may use as a starting point for a test that includes an additional cancer or two in the future. (PFF ¶¶ 701–706.) [redacted]

Response to Finding No. 728.1

[redacted]

[redacted]

728.2 [redacted]

Response to Finding No. 728.2

[redacted]

[redacted]

[redacted]

[redacted]

729. The overwhelming evidence showed that the purported MCED tests cited by Complaint Counsel are likely to be used very differently from Galleri in the event of launch. (PFF ¶¶ 730–736.)

Response to Finding No. 729

[redacted]

[redacted]

730. [redacted]

Response to Finding No. 730

[redacted]

730.1 As Bill Getty explained, "Galleri is going after something very different, which is just a larger population, test for more things. We are saying use us for colorectal cancer screening ostensibly when we are commercialized." (PX7040 (Getty (Guardant) IHT at 155–56).)

Response to Finding No. 730.1

The proposed finding is vague, misleading, and against the weight of the evidence. The proposed finding is vague and misleading to the extent Respondents are implying that Guardant is not development an MCED test because Respondents have taken a quote from Guardant's Bill Getty out of context. Mr. Getty was only testifying about Guardant's LUNAR-2 colorectal test in the portion of testimony that Respondents cite. (*See* PX7040 (Getty (Guardant) IHT at 155–56)). As a single-cancer test, the weight of the evidence shows that single-cancer tests, like Guardant's colorectal only test, will not compete with MCED tests. (*See* CCFF ¶¶ 660-87).

[redacted]

[redacted]

730.2 [redacted]

Response to Finding No. 730.2

[redacted]

730.3 [redacted]

Response to Finding No. 730.3

[redacted]

[redacted]

[redacted]

[redacted]

730.4 [redacted]

[redacted]

Response to Finding No. 730.4

[redacted]

[redacted]

730.5 [redacted]

Response to Finding No. 730.5

[redacted]

[redacted]

[redacted]

731. [redacted]

Response to Finding No. 731

[redacted]

[redacted]

[redacted]

731.1 [redacted]

Response to Finding No. 731.1

[redacted]

[redacted]

[redacted]

731.2 [redacted]

Response to Finding No. 731.2

[redacted]

[redacted]

[redacted]

731.3 [redacted]

Response to Finding No. 731.3

[redacted]

[redacted]

[redacted]

[redacted]

732. Helio. [redacted]

Response to Finding No. 732

[redacted]

[redacted]

732.1 Helio had previously developed a multi-cancer screening test called IvyGene but has since abandoned those efforts. (PFF ¶ 501.1.)

Response to Finding No. 732.1

This proposed finding is unsupported by factual evidence as it simply references another of Respondent's proposed findings. It also appears to be incorrect. When Helio operated under the name of LAM, Helio used the name "IvyGene" for the liver cancer screening tests now known as HelioLiver. (Chahine (Helio) Tr. 1001-02). Therefore, this Court should disregard the proposed finding.

732.2 Helio has only ever studied five cancers: breast, colon, liver, nasopharyngeal and lung. (RX3302 (Hao et al., 2017) at 1; RX3616 (Roy et al., 2019).)

Response to Finding No. 732.2

This proposed finding is relying on hearsay evidence and is misleading. The two documents Respondents cite above are academic articles reporting on studies of Helio's technology in breast, colon, liver, nasopharyngeal and lung cancers. It does not provide any evidence of Helio's internal research and development program. To the extent Respondents are relying upon these journal articles to prove the extent of Helio's internal research program it is unreliable hearsay evidence and should be given no weight. Therefore, this Court should disregard the proposed finding.

732.3 [redacted]

Response to Finding No. 732.3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

732.4 [redacted]

Response to Finding No. 732.4

[redacted]

[redacted]

733. [redacted]

Response to Finding No. 733

[redacted]

[redacted]

733.1 [redacted]

Response to Finding No. 733.1

[redacted]

[redacted]

733.2 [redacted]

Response to Finding No. 733.2

[redacted]

[redacted]

[redacted]

733.3 A test developer focusing on a single cancer screening test or a test directed to only a handful of targeted cancer types may elect to focus on the test's sensitivity, so it can serve as a "rule-out" test that does not require follow-up to confirm a negative result. As a corollary, in such tests, a lower level of specificity (and increase in the false-positive rate) can be tolerated, especially where there is a standard of care screening available that a doctor can reflex to, such as colonoscopy. (Cote Tr. 3829; RX3869 (Cote Expert Report) ¶ 95.)

Response to Finding No. 733.3

The proposed finding is unsupported as the only citations are to the unreliable and unqualified opinion testimony of Dr. Cote. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

734. FMI. FMI admittedly has no test. [redacted] (PX7074 (Perettie (FMI) Dep. at 79–80).) [redacted]

Response to Finding No. 734

[redacted]

[redacted]

735. Exact/Thrive. Exact/Thrive's CancerSEEK requires three separate tests to conclude a positive sample: first, a patient takes a baseline blood test, and if that returned a positive result, they then had a confirmation blood test. (Lengauer (Exact/Thrive) Tr. 246–48.) If both the baseline and the confirmatory blood tests were positive, then a patient would have to undergo a diagnostic full-body PET-CT scan to confirm the results of the blood testing and also to localize the potential cancer. (Lengauer (Exact/Thrive) Tr. 246–48.) [redacted]

Response to Finding No. 735

[redacted]

[redacted]

[redacted]

736. Singlera. Singlera's PanSeer assay has been shown to detect five types of cancer at 96.1% specificity in a retrospective, observational study of 418 participants. (RX3115 (Chen et al., 2020) at 1, 3.) On that measure alone, it is likely that Singlera would not be used in the same target population as Galleri. [redacted]

Response to Finding No. 736

[redacted]

[redacted]

737. This is further confirmed by the fact that any patient testing positive on PanSeer would then undergo an additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3115 (Chen et al 2020) at 6).)

Response to Finding No. 737

The proposed finding is unsupported and incorrect. Despite the ample evidence provided by Singlera, Respondents are citing a document not produced by the company. The proposed finding is incorrect to the extent Respondents are implying that Singlera is not offering tissue of origin capabilities with its PanSeer MCED test. Singlera's Scientific Advisor and former Chairman, Dr. Gary Gao, clearly testified that the PanSeer MCED test is designed to detect the tissue of origin. (Gao (Singlera) Tr. 2874). The document cited by Respondents merely suggest Singlera used an alternative means of identifying the tissue of origin during a clinical study using Singlera's PanSeer test.

Further, the proposed finding is incomplete and misleading to the extent Respondents are drawing a distinction with Grail's Galleri's cancer signal of origin ("CSO") performance by implying it has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population.

The CCGA study did not involve a real-world population, but rather was a case-control study that involved individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. (RX3430 at 10 (M.C. Liu, et al.,

Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Among other factors, some of the blood samples in CCGA were "collected from participants with cancer after biopsies had been carried out," which the authors note "could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." This Court should disregard the proposed finding.

738. [redacted] But the patient experience with the only version of the CancerSEEK test for which Exact/Thrive has published any data is very different from that same patient's experience with Galleri [redacted]

Response to Finding No. 738

[redacted]

[redacted]

739. The version of CancerSEEK used in the DETECT-A study consisted of three separate tests—two blood draws and a PET-CT scan that must each be collected at a different time (Lengauer (Exact/Thrive) Tr. 246–48)—makes it very different from Galleri, which consists of one blood draw that can be conducted as part of an annual physical exam. (PX0043 (GRAIL) at 112, 114.)

Response to Finding No. 739

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 53). Their only support for this alleged "fact" are testimony from Thrive's Christoph Lengauer testifying about a clinical trial on its CancerSEEK MCED test and Grail's own S-1 Form submitted to the SEC in September 2020. There is no citation to support an assertion that

Thrive's CancerSEEK is "very different" from Grail's Galleri.

Furthermore, Grail even identifies Thrive and its CancerSEEK MCED test as one of its competitors in this same S-1 Form. (PX0043 (Grail) at 033 ("We have competitors both in the United States and abroad, including . . . Thrive Earlier Detection, Corp.")). This is consistent with other evidence from Grail that identifies Thrive as its competitors. [redacted]

The proposed finding is also misleading to the extent it suggests that Galleri's algorithmic cancer signal of origin prediction is capable of definitively localizing cancer "through liquid biopsy alone." Reliable clinical data does not exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population. [redacted]

[redacted] Additionally, a positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.)

Interim results from PATHFINDER, an actual interventional trial for Galleri, indicate that additional imaging testing was required for positive results 90 percent of the time. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) ("Most participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)."). Over half the positive results in PATHFINDER with diagnostic resolution were determined to be false positives (55.4%) and 25 percent of participants who received falsely positive results underwent at least one invasive procedure. (RX3041 at 004 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

[redacted]

[redacted]

740. Moreover, a comparison between Galleri and the first blood draw in CancerSEEK further shows the significant differences between them. As shown in the table below, the performance of Galleri is superior to CancerSEEK's single blood draw:

Table 8

Test	Galleri	CancerSEEK 1 Blood Test
Study	CCGA3	DETECT-A
Types of Cancer	50	10
Cancer Signal of Origin	Yes	No
Specificity	99.5%	95.3%
Sensitivity	51.5%	30.2%
PPV	44.4%	5.9%

(*See* RX3409 (Klein 2021) at 5; RX3419 (Lennon et al., 2020) at 7).)

Response to Finding No. 740

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 53-54). Their only support for this alleged "fact" are copies of clinical reports done by Thrive and Grail on their respective MCED tests in development. There is no citation to support

Respondents' assertions that there are "significant differences between" Thrive's CancerSEEK and Grail's Galleri or that "the performance of Galleri is superior to CancerSEEK's single blood draw." These are merely legal arguments from Respondents that they have falsely claimed as "facts."

Respondents also rely on a table that they appear to have constructed and included in their proposed finding. The proposed finding is misleading because the weight of the evidence shows that the CCGA study is not indicative of Galleri's performance in the intended use (asymptomatic) population as explained below. Any attempt to compare directly the results in DETECT-A (an interventional study involving asymptomatic individuals) with CCGA (a case-control study involving diagnosed cancer patients, including patients with Stage IV cancer) meaningless and inherently unreliable. They are fundamentally different types of studies. Dr. Ofman of Grail conceded that "[t]o find all 50 cancer types in a real-world population would require hundreds of thousands of people[.]" (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298).

[redacted]

The authors of the CCGA-3 sub-study itself make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Accordingly, Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (i.e. in an asymptomatic screening population).

To put the above points plainly, a case control study will tend to produce inflated

performance results relative to how a test would performance in an asymptomatic screening population (the actual population in which MCED tests are intended to be used). Notwithstanding this, and notwithstanding the above admissions, Respondents nonetheless attempt to compare their case-control results to results from studies involving asymptomatic populations and pretend as if they are comparing apples to apples. They are not; the attempt itself is inherently misleading.

With respect to Grail's Galleri, the proposed finding is also misleading and incorrect to the extent Respondents are implying, as they do in their table, that Grail's Galleri can detect 50 cancers in an asymptomatic patient. [redacted]

The proposed finding is also incomplete and misleading to the extent it suggests, as it does in the table presented, that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet

exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population.

The proposed finding is also against the weight of the evidence that shows Grail routinely referring to Thrive and its CancerSEEK MCED as its competitor. [redacted]

740.1 [redacted]

Response to Finding No. 740.1

[redacted]

[redacted]

[redacted]

c. Unique production facilities

741. [redacted]

Response to Finding No. 741

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Cote as the only source of evidence supporting the proposed fact in contravention of this Court's Order. This Court should disregard this proposed finding. The proposed finding is also vague as it is unclear what "differences in how Grail is produced" this finding references. The proposed finding is also misleading to the extent Respondents intend to imply that the alleged differences in production facilities mean indicate that that Galleri is not in the same relevant market as other MCED test developers. As Complaint Counsel's Post-Trial Reply Brief explains, Respondents misapply this *Brown Shoe* factor. (Complaint Counsel's Post-Trial Reply Brief at Section I.B.).

741.1 As Nicole Berry explained, "[t]he mechanism by which a test provider translates the variant calls or the presence of absence of a combination of biomarkers into a clinically relevant conclusion is typically part of the proprietary piece of the workflow." (Berry (Illumina) Tr. 822.)

Response to Finding No. 741.1

This proposed finding is vague. It is unclear what is meant by a "clinically relevant conclusion." Otherwise, Complaint Counsel has no specific response to this proposed finding.

741.2 According to Ken Chahine, "[t]he magic occurs in basically deciphering the information you get back from that sequencing machine and determining what algorithm may or may not predict whether someone has cancer." (Chahine (Helio) Tr. 1015.)

Response to Finding No. 741.2

Complaint Counsel has no specific response to this proposed finding.

741.3 As part of the CCGA study, GRAIL determined that the most appropriate biomarker to identify early cancer through blood tests were methylation sites, in which plasma cfDNA is subjected to bisulfite conversion, prepared as a dual indexed sequencing library and enriched using standard hybridization capture conditions, followed by paired-end sequencing. (*See* RX3430 (Liu et al 2020) at 5.)

Response to Finding No. 741.3

[redacted]

[redacted]

741.4 GRAIL developed a proprietary method for library preparation to efficiently prepare methylated DNA fragments for sequencing, and then developed proprietary machine learning algorithms to take those methylation signals and make a prediction about whether or not a patient has cancer, and if they do, what type of cancer. (Aravanis (Illumina) Tr. 1887.)

Response to Finding No. 741.4

[redacted]

[redacted]

[redacted]

741.5 This approach is unique to GRAIL, [redacted]; Aravanis (Illumina) Tr. 1883 ("So the methylation patterns between different cancers can be quite different. Methylation patterns actually within a cancer, even of the same type that looks the same, can also be quite different. And this is actually why you need so many markers, which is that you need many markers to be able to understand which type of cancer, to distinguish it from someone who doesn't have cancer.").)

Response to Finding No. 741.5

[redacted]

741.5.1 There are about 30 million methylation sites in the human genome, and Galleri uses about one million of those. (Aravanis (Illumina) Tr. 1882–83; [redacted]

Response to Finding No. 741.5.1

This proposed finding is inaccurate. [redacted] Dr. Aravanis [redacted] testified that there are approximately one million methylation markers in the human genome informative for cancer, not that Galleri uses all of them. Therefore, this Court should disregard the proposed finding.

742. The library preparation and back-end algorithms used by the other putative MCED test developers are different from GRAIL's. (PFF ¶¶ 742.1–742.4.)

Response to Finding No. 742

[redacted]

742.1 Exact/Thrive is focusing only on 16 gene mutations and nine protein sites to screen for ten cancers. (*See* RX3419 (Lennon et al., 2020) at 4.)

Response to Finding No. 742.1

[redacted]

742.2 [redacted]

Response to Finding No. 742.2

[redacted]

742.3 Freenome's approach combines data from whole-genome sequencing, DNA methylation, and protein quantification using a multiomics approach. (RX3426 (Lin et al., 2021); RX3592 (Putcha et al., 2020).) [redacted]

Response to Finding No. 742.3

[redacted]

[redacted]

742.4 [redacted]

Response to Finding No. 742.4

[redacted]

d. Distinct customers

743. But what is clear already (and Complaint Counsel has not demonstrated otherwise) is that these tests will have different indications, and therefore distinct customers, from Galleri.

Response to Finding No. 743

This proposed finding is unsupported by any evidence and should be disregarded. The

proposed finding also should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). It is also incorrect insofar as it suggests that Complaint Counsel is has "not demonstrated otherwise." (*See* Complaint Counsel's Post-Trial Brief at Section II.B. and Complaint Counsel's Post-Trial Reply Brief at Section III.B.). Therefore, this Court should disregard the proposed finding.

744. The Galleri test can detect the presence of more than 50 cancers as well as the cancer signal of origin in positive cases. GRAIL expects Galleri will be ordered annually as part of a patient's annual physical exam. (PX0043 (GRAIL) at 112, 114.) The test is likely to be of interest to anyone above 50 who wishes to know whether they have cancer, regardless of location in the body, at an early stage through a single blood draw, without any need for a PET-CT scan and the risks such scans entail. (*See* Aravanis (Illumina) Tr. 1921–22; Ofman (GRAIL) Tr. 3315; Cote Tr. 3812.)

Response to Finding No. 744

The proposed finding is unsupported, misleading, and against the weight of the evidence. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. [redacted]

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population.

Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See*, e.g., RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See*, e.g., CCFF ¶ 6223). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection

and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

The implication a patient will only be willing to order a MCED if it does not involve a PET-CT scan is only supported by the biased testimony of Dr. Ofman and Dr. Aravanis and is contradicted by the weight of the record. The proposed finding is also misleading to the extent it implies that Galleri can reliably detect the tissue of origin. [redacted] Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-

CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

Grail undertook the PATHFINDER study to assess the extent and types of diagnostic testing that will be required to achieve diagnostic resolution following a positive Galleri result and tissue of origin prediction. (*See* RPFF ¶ 395 ("PATHFINDER's primary goal is to assess the extent and types of diagnostic testing required to achieve a diagnostic resolution after a patient has received a cancer screening test result that indicates 'Signal Detected', meaning the potential presence of cancer, along with a predicted or indeterminate tissue of origin.")). If Grail had already established the extent to which PET-CT and other types of diagnostic testing would be required to achieve diagnostic resolution when Galleri is used in a real-world setting, such a study would not be necessary. Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who

received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

[redacted] Therefore, this Court should disregard the proposed finding.

745. In contrast an MCED test capable of detecting only two or three cancer types would be used only by customers with reason to suspect susceptibility to the few cancers the test could detect, [redacted]

Response to Finding No. 745

[redacted]

[redacted]

746. [redacted]

Response to Finding No. 746

[redacted]

[redacted]

e. Distinct prices

747. At present, Galleri is the only MCED test with a price, currently selling for $949, (Bishop (GRAIL) Tr. 1322) [redacted]

Response to Finding No. 747

[redacted]

[redacted]

748. It is virtually impossible to compare Galleri to tests not yet in existence: as Bill Getty of Guardant testified, "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price." (PX7105 (Getty (Guardant) Dep. at 106–07).)

Response to Finding No. 748

This proposed finding is misleading because in the overall context of the question, Mr. Getty was being asked about a much broader market than MCED tests. The first question from Respondent's counsel asked Mr. Getty about the "oncology testing space" and the second question asked him about "blood-based screening market." (PX7105 (Getty (Guardant) Dep. at

106–07). Mr. Getty appeared confused and asked counsel for clarification in between the two questions. [redacted] By grouping different products with different functionalities together of course Mr. Getty testified that it "is difficult to speculate about the relevancy of price." This Court should disregard the proposed finding.

749. Complaint Counsel failed to show that any will have a similar price point to Galleri. (PFF ¶¶ 750.1–750.4.)

Response to Finding No. 749

This proposed finding is unsupported by any evidence as Respondents merely cited to another section of their findings and should be disregarded. [redacted] Therefore, this Court should disregard the proposed finding.

750. None of the putative MCED tests has a published price and no test developer has determined what the price of a putative MCED test might be. (PFF ¶¶ 750.1–750.4.)

Response to Finding No. 750

[redacted]

[redacted]

750.1 Singlera has said that it "couldn't know right now" at what price Singlera plans to market PanSeer. (PX7042 (Gao (Singlera) IHT at 99).)

Response to Finding No. 750.1

The proposed finding is misleading and out of context. Mr. Gao clarified that while he did not know the exact price, he did not know it would sell for less than $1,000 in the United States. (PX7042 (Gao (Singlera) IHT at 99). Moreover, this finding is misleading to the extent that it implies that there will not be price competition between the Galleri test and the PanSeer test. Rather, as Mr. Gao explains in that same investigational hearing transcript, "[e]very single company has to compete on that price front" with Grail's Galleri test. (PX7042 (Gao (Singlera) IHT at 99). **Therefore**, this Court should disregard the proposed finding.

750.2 [redacted]

Response to Finding No. 750.2

[redacted]

[redacted]

750.3 [redacted]

Response to Finding No. 750.3

[redacted]

[redacted]

[redacted]

[redacted]

750.4 There is no evidence to suggest any other putative MCED developer has made any determination on the price of any putative test that detects multiple cancer types. [redacted]

Response to Finding No. 750.4

[redacted]

[redacted]

751. While none of the putative MCED tests in development has an established price point, if they do not launch with comparable characteristics as Galleri, such as the number of cancers detected or the ability to detect cancer signal of origin, the evidence suggests they will not share the same price as Galleri. [redacted]

Response to Finding No. 751

[redacted]

[redacted]

[redacted]

f. Sensitivity to price changes

752. Just as it is impossible to compare the price of Galleri to the prices of tests not yet in the market, it is impossible today to say whether the price of Galleri will be sensitive to the availability and pricing of the putative tests in development. (*See* Getty (Guardant) Tr. 2678 ("Q. Based on what you know about healthcare markets and your determinations about competition between LUNAR-2 and Galleri, once LUNAR-2 is on the market at a given price, if that price were to increase by, let's say, $10, you could not say one way or another that that increase would cause doctors to prefer Galleri over LUNAR-2; right? A. No. Q. In other words, what I've just asked you is correct; you agree with my statement. A. Yes, I do.").)

Response to Finding No. 752

[redacted]

[redacted]

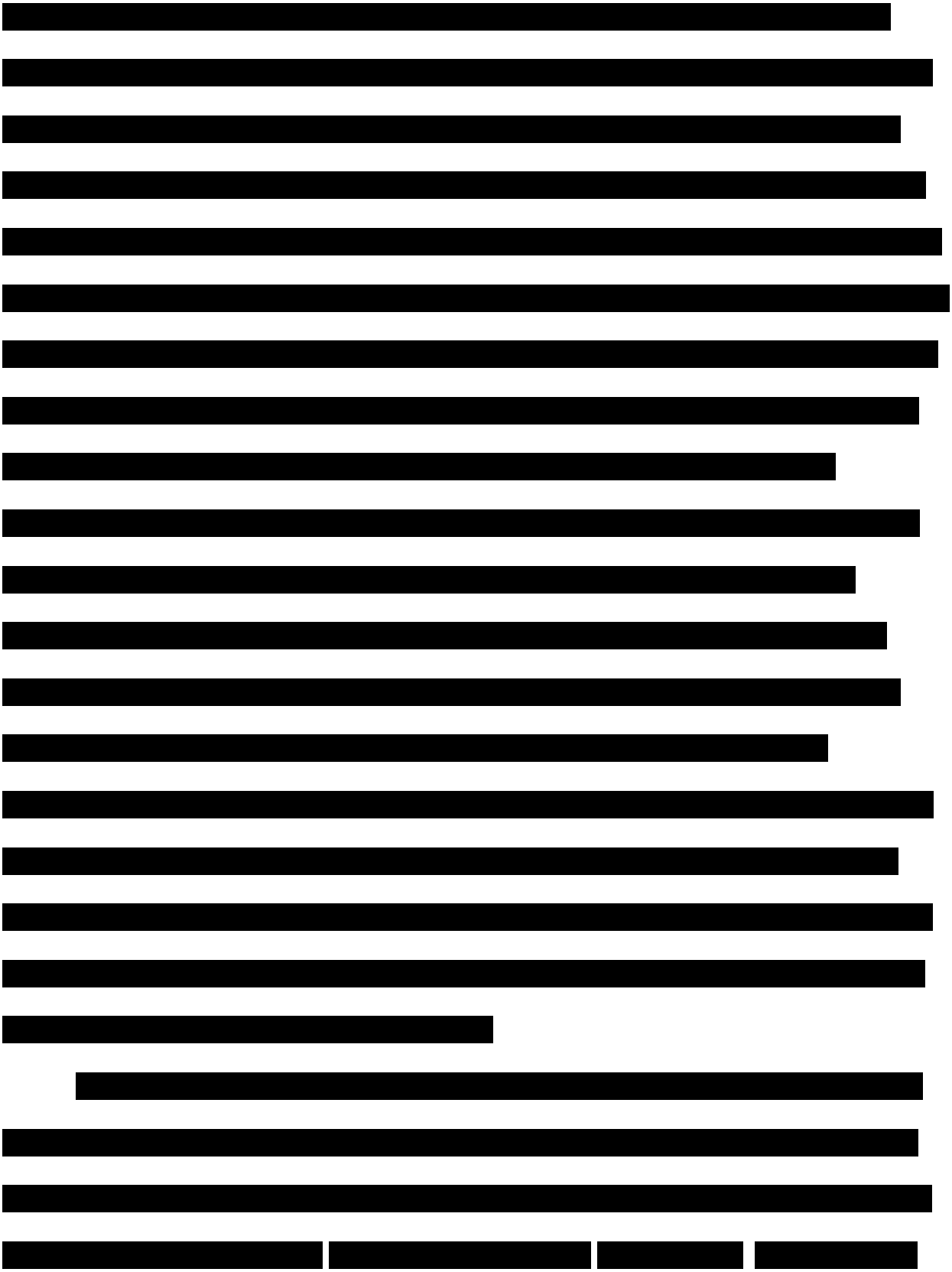
753. [redacted]

[redacted]

Response to Finding No. 753

[redacted]

[redacted]



[redacted]

754. On top of that, there is no record evidence that an increase in price to the 50-cancer test is likely to cause consumers to switch to a two- or three-cancer test. (RX6004 (Katz Trial Dep. at 18).)

Response to Finding No. 754

The proposed finding is unsupported, misleading, and against the weight of the evidence. The proposed finding is unsupported to the extent it relies on the impermissible opinion of Dr. Katz and is based on an incomplete hypothetical that does not reflect market realities.

Dr. Katz's opinion is unreliable and should disregarded. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). [redacted]

[redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Dr. Katz's opinion is should also be disregarded given that it is based on an incomplete hypothetical that is not based on market realities. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394 (Appendix B: Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. [redacted] The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect

those cancers early. (*See, e.g.,* CCFF ¶ 6223). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). [redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman,

acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

[redacted]

Therefore, this Court should disregard the proposed finding.

755. In any case, Complaint Counsel did not undertake any study concerning the price sensitivity of Galleri or any of the purported MCED tests in development. (RX6004 (Katz Trial Dep. at 20-23).)

Response to Finding No. 755

This finding is only supported by the impermissible expert opinion of Dr. Katz. [redacted]

[redacted] Given that that the sole support for this finding is Dr. Katz's impermissible opinion, this finding of fact should be disregarded in its entirety.

Aside from violating this Court's order, Dr. Katz's opinion is also inherently unreliable. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. [redacted]

[redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Finally, the proposed finding is also misleading to the extent Respondents are implying that Complaint Counsel has not [redacted] Therefore, this Court should disregard the proposed finding.

755.1 Indeed, they did not offer any evidence at all that the prices of Galleri will be sensitive to the changes in the prices of the MCED tests in development. (RX6004 (Katz Trial Dep. at 20-23).)

Response to Finding No. 755.1

This finding is only supported by the impermissible expert opinion of Dr. Katz. [redacted] Given that that the sole support for this finding is Dr. Katz's impermissible opinion, this finding of fact should be disregarded in its entirety.

Aside from violating this Court's order, Dr. Katz's opinion is also inherently unreliable. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert

report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023).

[redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Finally, the proposed finding is also misleading to the extent Respondents are implying that Complaint Counsel has not [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

756. It is undisputed that an MCED test's price will in part depend on the level of payor adoption, and that payor adoption will in large part depend on the development of extensive evidence to establish clinical utility of a MCED test. (*See* RX3867 (Deverka Expert Report) ¶ 92.)

Response to Finding No. 756

[redacted]

[redacted]

[redacted]

756.1 [redacted]

Response to Finding No. 756.1

[redacted]

[redacted]

g. Specialized vendors

757. While all purported MCED tests except for Galleri are still in early stages of development, all available evidence indicates that Galleri and the purported MCED tests in development have unique attributes which involve specialized vendors.

Response to Finding No. 757

This proposed finding unsupported by any evidence, let alone "all available evidence," should be disregarded.

758. Different vendors provide different medical services to patients. For example, a blood test may be performed in a physician's office by a phlebotomist, (RX3869 (Cote Expert Report) ¶ 127), while imaging or other scanning must be performed in a specialist offices and through other means, (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–16.)

Response to Finding No. 758

The proposed finding of fact is vague, misleading, and contradicted by the overwhelming weight of the evidence. This finding is vague because it's unclear what is meant by "different vendors" and "different medical services". This finding is also unsupported by the underlying citations as neither Dr. Aravanis nor Ms. Berry testified that imaging or scanning must be performed in a specialist offices or through other means. Given that this finding has no support it should be disregarded in its entirety. Moreover, the proposed finding is misleading to the extent it implies that the Galleri test will not need follow-up diagnostic work. As the Grail website explains, "A test result of 'Cancer Signal Detected' requires confirmatory diagnostic evaluation by medically establishing procedures (*e.g.* imaging) to confirm cancer." (PX0063 at 001 (Grail, Galleri Multi-Cancer Early Detection Test, https://grail.com/galleri/ (last visited Apr. 29, 2021))). [redacted]

[redacted]

759. Because the Galleri test is exclusively a blood test, it can be performed in a single physician's office alone. (*See* Bishop (GRAIL) Tr. 1402–03.)

Response to Finding No. 759

[redacted]

[redacted]

760. By contrast, Thrive's CancerSEEK assay entails at least two separate tests: one blood draw and the use of a PET-CT scan to confirm positive results and determine cancer signal of origin. (Lengauer (Exact/Thrive) Tr. 248–49.)

Response to Finding No. 760

[redacted]

[redacted]

761. Similarly, based on the current published data, a patient with a positive result from Singlera's PanSeer test could potentially undergo follow-up imaging to allow tissue of origin mapping. (RX3115 (Chen et al 2020) at 6.)

Response to Finding No. 761

[redacted]

762. [redacted]

Response to Finding No. 762

[redacted]

[redacted]

763. Should additional imaging be required to do so, those putative tests would likely require specialized vendors, that are not utilized in the routine workflow of the Galleri test, to provide a result to the patient. (*See* Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–16.)

Response to Finding No. 763

The proposed finding is vague to the extent it is unclear what "putative tests" it is referring to nor what it considers the "routine workflow of the Galleri test." The finding is unsupported as neither the testimony of Aravanis nor Berry discuss vendors needed by either the Galleri test or its rivals. Further neither Aravanis nor Berry have the foundation to testify about the workflow of non-Galleri MCEDs. As such, their unsupported, biased testimony should be disregarded in its entirety. [redacted] Therefore, this Court should disregard the proposed finding.

4. **Hypothetical Monopolist Test**

764. To show the hypothetical monopolist test is met here, Complaint Counsel relies exclusively on the testimony of Dr. Scott Morton. (CC Pretrial Br. at 47.)

Response to Finding No. 764

The proposed finding is misleading to the extent Respondents are implying that Complaint Counsel's market definition relies solely on the testimony and report of Dr. Scott Morton. Rather, as described in Complaint Counsel's post-trial briefing, Complaint Counsel relies on the extensive record in this case – including but not limited to Dr. Scott Morton's testimony – prove its alleged market. [redacted]

764.1 [redacted]

Response to Finding No. 764.1

[redacted] (*See See* PX7138 (Scott Morton Trial Dep. at 102–06, 181–82); *see generally* PX6090 (Scott Morton Expert Report).)

Response to Finding No. 764.2

[redacted]

765. Dr. Scott Morton did not conduct a SSNIP analysis based on quantitative purchase data.

Response to Finding No. 765

[redacted]

766. [redacted]

Response to Finding No. 766

[redacted]

767. In addition, Dr. Scott Morton did not attempt to fill the information gaps in her assessment using surveys or other means, including information about the preferences and likely switching behavior of clinicians, patients and payors related to the products she includes and excludes from her proposed MCED market. (RX3871 (Willig Expert Report) ¶ 21; RX6004 (Katz, Trial Dep. at 21).) She did not attempt to analyze substitution from the perspective of

payors, despite acknowledging that payor choices will drive adoption of different screening tests. (RX3871 (Willig Expert Report) ¶ 20.)

Response to Finding No. 767

The proposed finding is vague and misleading. The proposed finding is vague as it is unclear what "information gaps" it is referring to. Moreover, it is misleading to the extent it implies that [redacted] Therefore, this Court should disregard the proposed finding.

767.1 For instance, the need to obtain payor coverage of NGS-based screening tests will exert pressure on test developers to keep prices low when they commercialize their products. (*See* RX6004 (Katz, Trial Dep. at 19–20) ("[T]here's an information gap there then because we don't have the actual experience and she didn't, as far as I can tell certainly from her reports and her testimony, that she didn't attempt to fill those information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior."); [redacted]

Response to Finding No. 767.1

[redacted]

[redacted]

[redacted]

768. Dr. Scott Morton's failure to account for payor adoption in this way is compounded by her failure to assess how the possible characteristics of the MCED tests in development might impact the likelihood of switching within her defined market. [redacted]

Response to Finding No. 768

[redacted]

[redacted]

768.1 [redacted]

Response to Finding No. 768.1

[redacted]

768.2 [redacted]

Response to Finding No. 768.2

[redacted]

[redacted]

768.2.1 [redacted]

[redacted]

Response to Finding No. 768.2.1

[redacted]

[redacted]

768.2.2 [redacted]

Response to Finding No. 768.2.2

[redacted]

[redacted]

768.3 [redacted]

Response to Finding No. 768.3

[redacted]

[redacted]

768.4 [redacted]

Response to Finding No. 768.4

[redacted]

[redacted]

[redacted]

[redacted]

768.5 [redacted]

Response to Finding No. 768.5

[redacted]

769. [redacted]

Response to Finding No. 769

[redacted]

769.1 [redacted]

[redacted]

Response to Finding No. 769.1

[redacted]

[redacted]

770. [redacted]

Response to Finding No. 770

[redacted]

5. **Subjective and Changing Policy Assessments**

771. Complaint Counsel seeks to dismiss the shortcomings in its proof by asserting that the relevant market is nascent and that there is limited evidence available to it. (*See* CC Pretrial Br. at 31.) It suggests that the law is specially written to protect nascent markets and that such markets are not inoculated from application of the antitrust laws. (*See* CC Pretrial Br. at 31.)

Response to Finding No. 771

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial

Brief at 70-71). [redacted] Therefore, this Court should disregard the proposed finding.

772. Dr. Scott Morton has not performed the analysis necessary to define an innovation market. (RX6004 (Katz Trial Dep. at 26) ("If she had been doing an innovation market, she should have been asking a different question about the hypothetical monopolist. You would ask the question did a hypothetical monopolist that controlled some set of assets to innovation -- you know, you already think of those as easier just think of controlled a bunch of firms that were innovators -- could it find it profitable to cut back on innovation. And thinking about the boundaries of the market, you'd be focusing on capabilities to do innovation. You'd be looking at different factors. I think it's clear that Professor Scott Morton when she applies her hypothetical monopolist test is applying it to defining a product market, not an innovation market.").)

Response to Finding No. 772

The proposed finding is not supported. [redacted]

Here, Respondents fail to point to any corresponding analysis from Dr. Willig's expert report. Indeed, they cannot because Dr. Willig offered no opinion regarding the requirements for defining an innovation market or whether Dr. Scott Morton had fulfilled said requirements. (RX3871 (Willig Expert Report) ¶¶ 6-8). Given that Respondents' assertion is based solely on impermissible expert opinion testimony it should be disregarded. Moreover, Respondents' arguments fail for all the reasons stated in Complaint Counsel's Post-Trial Reply Brief.

[redacted] Therefore, this Court should disregard the proposed finding.

B. The Alleged Related Product Market

1. No Proof to Support Alleged Related Product Market

773. Complaint Counsel defines the related product market as "Illumina's NGS instruments and consumables". (CC Pretrial Br. at 49; Complaint ¶ 50 ("Illumina's NGS platform is the related product".) The narrowness of this alleged market, in which Illumina would obviously be a monopolist (as it would necessarily be the only supplier), stands in stark contrast to the very broad manner in which Complaint Counsel seeks to define the relevant product market. (*See* PFF V.A.)

Response to Finding No. 773

The proposed finding should be disregarded because it is not a "finding of fact" but a legal argument pulled directly from Respondent's post-trial brief and inappropriately mischaracterized as a fact. (*See* Respondents' Post Trial Brief at 76). Moreover, it misstates Complaint Counsel's legal arguments regarding the related product at issue. [redacted] Given its complete and utter failure to abide this Court's order and the Part 3 rules and the FOF's inaccuracy, this finding should be disregarded in its entirety. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

774. In discussing the relevant product market, Complaint Counsel acknowledges that an appropriate antitrust market is dependent on reasonable interchangeability, the *Brown Shoe* practical indicia and the hypothetical monopolist test. (*See* CC Pretrial Br. at 30–48.)

Response to Finding No. 774

The proposed finding should be disregarded because it is not a "finding of fact" but a

legal argument pulled directly from Respondent's post-trial brief and inappropriately mischaracterized as a fact. (*See* Respondents' Post Trial Brief at 76). Given its complete and utter failure to abide this Court's order and the Part 3 rules, this finding should be disregarded in its entirety. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

775. Neither Complaint Counsel nor its expert (Dr. Scott Morton) does the requisite analysis, despite the availability of quantitative data. Complaint Counsel says simply that MCED test developers prefer Illumina's NGS instruments and consumables to the alternatives. (FTC Pretrial Br. at 53–57; [redacted]

Response to Finding No. 775

[redacted]

[redacted]

2. Current NGS Platform Alternatives to Illumina

776. Contrary to Complaint Counsel's unproven contention, there are other viable NGS platforms on the market that can support MCED tests in development.

Response to Finding No. 776

The proposed finding should be disregarded because it is not a "finding of fact," but rather an argument in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Respondents' Post-Trial Brief at 95). The proposed finding is "vague" because it does not define what "viable NGS platforms" or "that can support MCED tests in development" means. This proposed finding is also unsupported, citing no evidence, and should be disregarded. [redacted]

777. BGI. BGI already has a commercially available NGS platform, markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]

Response to Finding No. 777

[redacted]

[redacted]

[redacted]

777.1 BGI is currently enjoined from launching its sequencing instruments and related reagents in the United States due to its infringement of a certain Illumina patents that expire in 2022 and 2023. (RX3356 (Businesswire); RX3869 (Cote Expert Report) ¶ 287.)

Response to Finding No. 777.1

Complaint Counsel objects to this proposed finding as incomplete, improper expert opinion, and unreliable.

Although Complaint Counsel does not disagree with the fact that "BGI is currently enjoined from launching its sequencing instruments and related reagents in the United States," this proposed finding is incomplete in that it suggests Illumina is seeking injunctive relief against BGI based only on patents that expire in 2022 and 2023. [redacted] Furthermore, the Business Wire article cited to support this proposed finding is dated June 16, 2020. More recently in February 2021, Illumina's executive Dr. Aravanis represented to investors that that Illumina has alleged that BGI infringed patents that expire after 2023, ranging from 2024 to 2027 and hinted at future patent lawsuits noting that "[a]s we learn more about BGI's products, additional patents may become relevant." (PX2822 (Illumina) at 006-007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021; *see also* deSouza (Illumina) Tr. 2231).

Respondents also cite their expert, Dr. Cote, inappropriately to support a factual proposition. This Court held that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Accordingly, this Court should disregard this evidence. Lastly, to the extent Respondents are claiming that it is Dr. Cote's expert opinion that Illumina's patents are preventing BGI's entry into the U.S. market until 2023, Dr. Cote has no basis to testify about Illumina's patent position. [redacted] For this reason, any expert opinion offered by Dr. Cote regarding BGI's future freedom to operate in the United States is not only improper expert opinion but also completely lacks foundation. [redacted] Therefore, with the exception of the specific language with which Complaint Counsel does not disagree, this Court should disregard the proposed finding.

> 777.2 BGI may enter the U.S. market by August 2022. *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the patents-in-suit—as they are permitted—they must include the following conspicuous written disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'")

Response to Finding No. 777.2

The proposed finding is unsupported in that the court order cited does not provide that "BGI may enter the U.S. market by August 2022." The court order *bars* BGI from entering until after August 23, 2022, but it in no way purports to authorize or permit BGI to "enter the U.S. market" as of that date, nor could it. The federal court in the Northern District of California ruled solely on the case or controversy before it, which involved the limited set of U.S. patents Illumina chose to assert *in that lawsuit only*. The court determined nothing whatsoever regarding other patents, lawsuits, or other legal obstacles that may well block BGI from entering the U.S. market long after August 23, 2022.

The proposed finding is incomplete and misleading in that it suggests Illumina is only seeking injunctive relief against BGI through the suit captioned *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal.), in federal court in the Northern District of California. [redacted]

Moreover, Illumina holds additional patents touching "every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina's significant investments in research and development" that extend to beyond 2030 and which "may become relevant" against BGI. (deSouza (Illumina) Tr. 2231-2232; PX2822 (Illumina) at 006-007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)). Therefore, this Court should disregard the proposed finding.

To the extent this proposed finding purports to suggest that BGI intends to launch its NGS platform in the U.S. in 2022 notwithstanding Illumina's pending patent infringement suit, Respondents have no evidence to support that claim. Respondents elected not to pursue any form of discovery from BGI in this action. Therefore, this Court should disregard the proposed finding.

777.3 [redacted] RX3869 (Cote Expert Report) ¶ 287; *see also* [redacted]

Response to Finding No. 777.3

[redacted]

[redacted]

[redacted]

777.4 BGI's DNBSEQ sequencer's reported accuracy is comparable to Illumina's sequencers, and guarantees >80% of bases with quality score of >Q30 (over 99.9% accurate). (RX3465 (MGI Tech); RX3067 (BGI) at 1.)

Response to Finding No. 777.4

[redacted]

[redacted]

777.5 [redacted]; Cote Tr. 3743–44; RX3869 (Cote Expert Report) ¶ 287.)

Response to Finding No. 777.5

[redacted]

[redacted]

778. Thermo Fisher. [redacted]

Response to Finding No. 778

[redacted]

[redacted]

[redacted]

778.1 [redacted]

Response to Finding No. 778.1

[redacted]

[redacted]

778.2 [redacted]

Response to Finding No. 778.2

[redacted]

[redacted]

[redacted]

779. Oxford Nanopore. In addition to BGI and Thermo Fisher, Oxford Nanopore is also a viable alternative for MCED developers. (RX3521 (NCM) at 50–51; RX3167 (ONT); RX3520 (NCM) at 6, 9–10; RX3869 (Cote Expert Report) ¶ 268.)

Response to Finding No. 779

[redacted]

[redacted]

[redacted]

779.1 ONT's recent improvements, such as adaptations to its sequencers and library preparation, has made its platform more suitable for multi-cancer screening. (*See* RX3441 (Marcozzi et al., 2020); RX3446 (Martignano et al., 2021); RX3869 (Cote Expert Report) ¶¶ 293, 295–98.)

Response to Finding No. 779.1

This proposed finding is vague, confusing, unsupported, misleading, and relies on hearsay evidence, improper expert testimony, and is against the weight of the evidence.

The proposed finding is vague and confusing because it does not describe what is meant by "recent improvements" or "adaptations to its sequencers and library prep" or why these changes purportedly make ONT's NGS platform more suitable for MCED test developers than prior to those changes. Furthermore, Respondents cite two academic journal articles to support this proposed finding. To the extent Respondents are citing these articles to support the factual proposition that ONT's has, in fact, made changes to its sequencers and library prep that would make these platforms more suitable for MCED test developers that is an out of court statement being offered for the truth of the matter asserted and hearsay evidence. As such, the Court ought not give this evidence any weight. Respondents did not obtain any documents or testimony from ONT through discovery and therefore cannot point to any evidence directly from ONT about any adaptions ONT has made to its platform, or how those adaptations might change the commercial applications of ONT's long-read NGS platform.

[redacted]

[redacted]

Respondents yet again rely upon their own unreliable expert Dr. Cote. Dr. Cote's is not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED testing, because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). This Court should not accord Dr. Cote's opinion any weight. [redacted] Furthermore, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). To the extent Respondents are attempting to use Dr. Cote's report to support any factual proposition about ONT's NGS platform's capabilities or improvements, that is improper and the Court should disregard that evidence.

Given Respondents' reliance on unreliable, improper expert testimony and hearsay, this Court should disregard this finding.

> 779.2 ONT's instruments reportedly will compete with Illumina's on throughput, accuracy and cost. ONT's highest throughput instrument, the PromethION, has a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell. (RX3543 (ONT); RX1205 (Illumina); RX3869 (Cote Expert Report) ¶ 294.)

Response to Finding No. 779.2

[redacted]

[redacted]

[redacted]

779.3 ONT's claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) And, as shown in the table below, ONT may offer per Gb sequencing costs that are lower than what Illumina offers.

Response to Finding No. 779.3

[redacted]

[redacted]

[redacted]

[redacted]

For Complaint Counsel's Response to the Table referenced in this proposed finding *see* Complaint Counsel's Response to RPFF ¶ 780, below.

780. Liquid biopsy test makers view these platforms as viable substitutes for Illumina's platform:

Response to Finding No. 780

This proposed finding is completely unsupported and should be disregarded as Respondents cite no evidence. [redacted] Therefore, this Court should disregard the proposed finding.

780.1 [redacted] *see also* RX3062 (Natera).)

Response to Finding No. 780.1

[redacted]

[redacted]

[redacted]

780.2 [redacted]

Response to Finding No. 780.2

[redacted]

[redacted]

780.3 [redacted]

Response to Finding No. 780.3

[redacted]

780.4 Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment. (Gao (Singlera) Tr. 2928.)

Response to Finding No. 780.4

This proposed finding is misleading and inaccurate as respondents omitted highly relevant testimony that clearly demonstrates that Singlera's Dr. Gao does NOT view Thermo Fisher's NGS platform to be a suitable alternative to Illumina's NGS platform. Dr. Gao testified at trial that Thermo Fisher is "not going to be a viable alternative" for its PanSeer test and it has no plans to switch to Thermo Fisher's NGS platform (Gao (Singlera) Tr. 2894; [redacted] Therefore, this Court should disregard the proposed finding.

780.5 [redacted]

Response to Finding No. 780.5

[redacted]

780.6

Response to Finding No. 780.6

781.

RX3543 (ONT) at 2; RX3258 (Genengnews).)

Response to Finding No. 781

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

3. Promising NGS Sequencers in Development and Likely Entrants

782. In addition to the viable platforms on the market, there are also many NGS platforms in development and likely to enter the market in the near future that will be viable platforms for MCED tests. (Cote Tr. 3923; *see* PFF ¶¶ 782.1–787.)

Response to Finding No. 782

[redacted]

[redacted]

[redacted]

782.1 [redacted]

Response to Finding No. 782.1

[redacted]

[redacted]

783. Singular Genomics. Singular Genomics has developed an NGS platform, the G4 System, which launched at the end of 2021 and expects to begin shipping units in the second quarter of 2022. (RX4048 (Singular); Velarde (Singular) Tr. 4515–16; (PX8561 (Singular) at 1; PX7117 (Velarde (Singular) Dep. at 30); RX3869 (Cote Expert Report) ¶ 301).)

Response to Finding No. 783

[redacted]

[redacted]

[redacted]

783.1 The G4 Systems's performance characteristics claim to be comparable to that of Illumina's NextSeq and NovaSeq systems, with read lengths of 50 to 150 bases, targeted 400 Gbs per sequencing run, high speed sequencing at 4–minute cycle times and high accuracy of 99.7% on 150 base reads. (PX8561 (Singular) at 4–5; [redacted]

Response to Finding No. 783.1

[redacted]

[redacted]

[redacted]

783.2 [redacted]

Response to Finding No. 783.2

[redacted]

[redacted]

783.3 [redacted]

Response to Finding No. 783.3

[redacted]

[redacted]

784. Ultima Genomics. [redacted]

Response to Finding No. 784

[redacted]

[redacted]

[redacted]

784.1 [redacted]

Response to Finding No. 784.1

[redacted]

[redacted]

784.2 [redacted]

Response to Finding No. 784.2

[redacted]

[redacted]

[redacted]

784.3 [redacted]

Response to Finding No. 784.3

[redacted]

[redacted]

784.4 [redacted]

Response to Finding No. 784.4

[redacted]

[redacted]

[redacted]

784.5 [redacted]

Response to Finding No. 784.5

[redacted]

[redacted]

[redacted]

784.6 [redacted]

Response to Finding No. 784.6

[redacted]

[redacted]

[redacted]

[redacted]

785. Roche. [redacted]

Response to Finding No. 785

[redacted]

[redacted]

785.1 [redacted]

Response to Finding No. 785.1

[redacted]

[redacted]

785.2 [redacted]

Response to Finding No. 785.2

[redacted]

[redacted]

785.3 [redacted]

[redacted]

Response to Finding No. 785.3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

786. Element. [redacted]

Response to Finding No. 786

[redacted]

[redacted]

786.1 [redacted]

Response to Finding No. 786.1

[redacted]

[redacted]

[redacted]

786.2 [redacted]

Response to Finding No. 786.2

[redacted]

[redacted]

[redacted]

786.3 [redacted]

Response to Finding No. 786.3

[redacted]

[redacted]

[redacted]

787. Omniome. Omniome, recently acquired by PacBio (RX3552 (GenomeWeb) at 1), is developing an NGS sequencer using its sequencing-by-binding technology. (RX3533 (Omniome) at 1.)

Response to Finding No. 787

Complaint Counsel has no specific response to this finding.

787.1 [redacted]—"10 to 100x better than" the accuracy of Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 82).)

Response to Finding No. 787.1

[redacted]

[redacted]

787.2 Omniome expects that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. PX7096 (Song (Omniome) Dep. at 43, 58); [redacted] RX3869 (Cote Expert Report) ¶ 319.)

Response to Finding No. 787.2

[redacted]

[redacted]

[redacted]

[redacted]

787.3 [redacted]

Response to Finding No. 787.3

[redacted]

[redacted]

[redacted]

788. [redacted]

Response to Finding No. 788

[redacted]

[redacted]

789. Complaint Counsel bases its alleged market definition on speculation about future entry by early-stage developmental MCED tests (*see* Section I.A above), while simultaneously

discarding evidence of actual competition and future entry by NGS developers in defining the alleged related product market. (*See* RX6000 (Carlton Trial Dep. at 37–38) ("[A]ll I can do is point out the asymmetry in [Complaint Counsel's] analysis . . . in which [it] assumes that the MCED products are going to come into existence, but the NGS alternatives to Illumina are not.")

Response to Finding No. 789

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion and an argument in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 82-83).

4. Adapting Assays Developed on Illumina's Platforms to Another Platform

790. [redacted]

Response to Finding No. 790

[redacted]

[redacted]

791. It is likely that a test developer will need to switch between different sequencing platforms (such as between different Illumina NGS platforms) during the course of developing a screening test, even absent the acquisition. (Cote Tr. 3739, 3771; Aravanis (Illumina) Tr. 1865.)

Response to Finding No. 791

Complaint Counsel objects to the proposed finding because it cites only unreliable and unfounded self-serving testimony, against the weight of the evidence, and it improperly cites expert testimony.

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; and his previous prediction of upstream entry was wrong casting doubt on similar analysis in this case. (*See* Response to RPFF ¶ 1959, below, (setting forth Dr. Cote's credibility problems across these subjects)). Dr. Cote is not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test because he has no experience developing such tests. (*See* Response to RPFF ¶ 1960, below, (examining Dr. Cote's lack of qualifications on subject of MCED development process and timeline)). Dr. Cote is not qualified to provide expert opinion testimony about which NGS platforms are viable for MCED

testing because he has never operated an NGS instrument and has no publications related to NGS, among other reasons. (*See* Response to RPFF ¶ 1964, below, (examining Dr. Cote's lack of qualifications on subject of which NGS platforms are viable for MCED testing)). With no expertise developing multicancer tests nor operating NGS equipment he has no basis to offer an opinion on the likelihood, process, or difficulty of switching NGS platforms for MCED test developers. In addition to Dr. Cote being unqualified and not credible, his opinion about any test developer switching platforms is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote for support for the purported facts in the proposed finding in contravention of this Court's Order. Dr. Cote has no personal knowledge or experience regarding switching an MCED test from one NGS platform to another (or developing an MCED test on any platform). This Court should disregard this evidence.

Dr. Aravanis's testimony that Respondents rely upon for this proposed finding is unfounded, and contrary to the weight of the evidence. First, Complaint Counsel objects to Illumina's Chief Technology Officer Dr. Aravanis's testimony about the difficulty, length of time, and cost associated with any MCED test developer switching from one NGS platform to another as lacking foundation. The testimony that Respondents cite to is Dr. Aravanis speculating about what it would take for Grail to switch between different models of Illumina sequencers. As Grail never did so, and Dr. Aravanis is currently an Illumina executive, Dr.

Aravanis has no basis upon which to speculate about the length of time and process involved if Grail were to switch NGS sequencers. He has absolutely no basis to opine on any other MCED test developer's ability to switch NGS platforms including the length of time it would take and the difficulty. He admitted he has no access to confidential and proprietary information including technical requirements for NGS sequencing, or the specifications of the multicancer assay for any MCED test developer, including Guardant, , Freenome, Exact, Helio, and Singlera (Aravanis (Illumina) Tr. 1975).

Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

791.1 Test developers routinely re-validate their tests to account for new developments in their tests, new and improved technology relating to consumables or sequencers, or for any number of other reasons. (RX3869 (Cote Expert Report) ¶ 338.) These revalidations are integral to a sound business plan for any test developer. (RX3869 (Cote Expert Report) ¶ 338.)

Response to Finding No. 791.1

[redacted]

[redacted]

e

[redacted]

792. [redacted]

Response to Finding No. 792

[redacted]

[redacted]

793. Other screening test developers have, in fact, switched platforms for their MCED tests in development. (PFF ¶¶ 793.1–793.4.)

Response to Finding No. 793

Complaint Counsel objects to this proposed as completely unsupported. This finding is essentially a header to the below section and should be disregarded.

793.1 For example, during Thrive's initial development of the CancerSEEK test, including for the DETECT-A study, Thrive used Illumina's HiSeq 4000 and MiSeq instruments as its NGS platforms. [redacted]; RX3419 (Lennon et al 2020) at 18; [redacted]

Response to Finding No. 793.1

[redacted]

793.2 [redacted]

Response to Finding No. 793.2

[redacted]

[redacted]

793.3 [redacted]

Response to Finding No. 793.3

Complaint Counsel does not disagree with this finding.

793.4 [redacted]

Response to Finding No. 793.4

[redacted]

[redacted]

[redacted]

794. Given the increased availability of competing NGS platforms in the next few years, screening test developers have many opportunities to switch from Illumina's platform to another platform, with a process no more burdensome than that they would use to switch to the next generation of Illumina sequencers. (RX3869 (Cote Expert Report) ¶ 271.)

Response to Finding No. 794

[redacted]

[redacted]

[redacted]

[redacted]

795. [redacted]

Response to Finding No. 795

[redacted]

[redacted]

796. [redacted]

Response to Finding No. 796

[redacted]

[redacted]

VI. COMPLAINT COUNSEL FAILED TO PROVE THE TRANSACTION IS LIKELY TO SUBSTANTIALLY LESSEN COMPETITION

A. Vertical Mergers

797. Vertical mergers do not raise the same concerns as horizontal mergers because they do not involve the combination of substitutable products and the reduction of competition between those products. (RX6000 (Carlton Trial Dep. at 16).)

Response to Finding No. 797

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* Rule 3.46; Order on Post-Trial Findings). Additionally, the proposed finding is conclusory, and misstates the record to the extent that the cited testimony contains no mention of substitutable products or a reduction in competition between products. Moreover, the proposed finding is contrary to established economic and legal literature which demonstrates the significant anticompetitive effects which can result from vertical mergers. (*See generally* CCCL ¶¶ 11-12; 39-42; 47-51). Finally, the proposed finding is incorrect and misleading to the extent it suggests that Illumina's acquisition of Grail cannot be anticompetitive because it is vertical in nature. The weight of the evidence demonstrates the competitive harm that is likely to result from the proposed acquisition. (*See generally* CCFF ¶¶ 2607-4164; CCCL ¶¶ 39-60). Therefore, this Court should disregard the proposed finding.

798. Vertical mergers can harm competition only in narrow circumstances. (RX3864 (Carlton Expert Report) ¶ 43; RX6000 (Carlton Trial Dep. at 15–24.)

Response to Finding No. 798

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* Rule 3.46; Order on Post-Trial Findings). The proposed finding is also vague to the extent that "narrow circumstances" is undefined, and incorrect and misleading to the extent that the finding

suggests that vertical mergers cannot produce anticompetitive effects. The proposed finding is contrary to established economic and legal literature which demonstrates the significant anticompetitive effects which can result from vertical mergers. (*See generally* CCCL ¶¶ 11-12; 39-42; 47-51). The proposed finding is incorrect and contrary to the weight of the evidence to the extent it suggests that the proposed acquisition is not anticompetitive because it will not result in raising rivals' costs (the "narrow circumstances" acknowledged by Respondents' expert, Dr. Carlton). The weight of the evidence demonstrates that, post-deal, Illumina would have both the ability and incentive to foreclose or reduce the competitiveness of Grail's MCED test rivals by virtue of its ownership of irreplaceable NGS technology. (*See* CCFF ¶¶ 2607-4164). Finally, the proposed finding is incorrect and misleading to the extent it suggests that Illumina's acquisition of Grail cannot be anticompetitive because it is vertical in nature. The weight of the evidence demonstrates the competitive harm that is likely to result from the proposed acquisition. (*See generally* CCFF ¶¶ 2607-4164; CCCL ¶¶ 39-60)). Therefore, this Court should disregard the proposed finding.

799. A vertical merger involves combining firms that have complementary assets. (RX3864 (Carlton Expert Report) ¶¶ 42, 54; RX6000 (Carlton Trial Dep. at 16:7–24; 17:7–24.)

Response to Finding No. 799

[redacted]

[redacted]

800. Most vertical mergers are likely to generate significant efficiencies for reasons that are well understood in the literature. (RX3864 (Carlton Expert Report) ¶¶ 42, 52; RX6000 (Carlton Trial Dep. at 15–18.)

Response to Finding No. 800

[redacted]

[redacted]

800.1 It is well known that when two firms with complementary assets combine, it can eliminate transaction costs that enable procompetitive collaboration that would not be achieved by the firms in an arm's-length relationship. (RX6000 (Carlton Trial Dep. at 16.)

Response to Finding No. 800.1

[redacted]

[redacted]

800.2 The efficiency benefits from vertical integration can provide a powerful motivation for a vertical merger and can eliminate any concerns about potential adverse competitive impacts since efficient mergers lead to lower prices and/or improvements in the quality or availability of products, all of which benefit consumers. (RX3864 (Carlton Expert Report) ¶ 42; RX6000 (Carlton Trial Dep. at 16.)

Response to Finding No. 800.2

[redacted]

[redacted]

800.3 As Commissioner Wilson as noted, "[e]conomists have conducted a number of retrospective studies of vertical mergers. Most suggest that consumers benefit. For example, LaFontaine and Slade found in a 2007 survey that 'efficiency considerations overwhelm anticompetitive motives in most contexts.' A 2005 survey by four FTC economists found similar results. So did a 2018 survey by economists at the Global Antitrust Institute." (RX4008 (Wilson).)

Response to Finding No. 800.3

[redacted]

800.4 A single firm able to coordinate how these assets are used may be able to streamline production, inventory management or distribution. (RX3701 (FTC) at 13; RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 17–18, 57.)

Response to Finding No. 800.4

[redacted]

800.5 It may also be able to create innovative products in ways that would not likely be achieved through arm's-length contracts. (RX3701 (FTC) at 13; RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 17–18, 57.)

Response to Finding No. 800.5

[redacted]

[redacted]

800.6 Such efficiencies are particularly important in industries that are characterized by high levels of R&D expenditures and where firms are unwilling to share their valuable, proprietary knowledge with others, absent a merger. (RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 57.)

Response to Finding No. 800.6

[redacted]

[redacted]

800.7 Efficiencies that bring products to market more quickly and facilitate more productive R&D efforts benefit consumers directly. (RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 17–18, 57.)

Response to Finding No. 800.7

[redacted]

[redacted]

[redacted]

801. An analysis of a vertical merger that ignores evidence of merger-specific efficiencies is incomplete and likely to arrive at an unsupportable conclusion. (RX3864 (Carlton Expert Report) ¶ 54.)

Response to Finding No. 801

[redacted]

801.1 [redacted]

Response to Finding No. 801.1

[redacted]

[redacted]

B. Importance of a Full Economic Model

802. A complete analysis of a vertical merger requires an economic model that accurately reflects the upstream and downstream markets in which the merging firms operate. (RX3864 (Carlton Expert Report) ¶¶ 51–55; RX6000 (Carlton Trial Dep. at 24:6–25:10.)

Response to Finding No. 802

[redacted]

[redacted]

803. A full economic model must simultaneously accounts for the change in incentives to price to downstream rivals (bearing in mind the impact of post-merger contractual and reputational constraints) as well as any efficiencies, while taking into consideration any constraints on the firms' behavior. (RX3864 (Carlton Expert Report) ¶¶ 51–55; RX6000 (Carlton Trial Dep. at 24–25.)

Response to Finding No. 803

[redacted]

[redacted]

803.1 As Dr. Carlton testified "[i]f you don't take account of the efficiencies or, more broadly, the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've failed to balance the benefits against the possible harms." (RX6000 (Carlton Trial Dep. at 26).)

Response to Finding No. 803.1

[redacted]

804. The outcome of a vertical model is influenced by a number of factors, including (i) the efficiencies arising from the merger, (ii) the incentives on the merged firm that can exert downward pricing pressure, (iii) the merged firms' profit margins, (iv) the demand curves of each of the merging firms, (v) the diversion ratios of the downstream product (that is, the share of downstream rivals' sales that would divert to the merged firm in response to an upstream price increase), (vi) the competitive forces facing the upstream firm, (vii) the cost of the upstream inputs relative to downstream revenues and margins, (viii) downstream product differentiation, and (ix) any reputational and contractual constraints on the merged firm. (RX3864 (Carlton Expert Report) ¶¶ 44–50; RX6000 (Carlton Trial Dep. at 24.)

Response to Finding No. 804

[redacted]

[redacted]

804.1 [redacted]

Response to Finding No. 804.1

[redacted]

805. The economic model must also take account of the "timing and magnitude of potential harm versus likely benefit" because "if the harms are far off in the future, but the benefits are closer in", that critical balance of potential harms versus benefits would be skewed and a procompetitive vertical merger could, as a result, be disallowed, depriving consumers of enormous benefits. (RX6000 (Carlton Trial Dep. at 25–26).)

Response to Finding No. 805

[redacted]

[redacted]

806. Only with such a model could one make a judgment as to whether the merger would likely result in net harm to consumers. (RX3864 (Carlton Expert Report) ¶ 55; RX6000 (Carlton Trial Dep. at 24–25).)

Response to Finding No. 806

[redacted]

[redacted]

807. If an economic model fails to reflect the efficiency benefits of a vertical merger and balance those effects against the possible harms, it creates the risk of preventing a merger that would bring large benefits to society. (RX6000 (Carlton Trial Dep. at 25 –26).)

Response to Finding No. 807

[redacted]

C. Complaint Counsel Failed to Present a Full Economic Model Supporting the Alleged Harms

808. [redacted]

Response to Finding No. 808

[redacted]

[redacted]

809. [redacted]

Response to Finding No. 809

[redacted]

[redacted]

810. [redacted]

Response to Finding No. 810

[redacted]

811. Complaint Counsel and Dr. Scott Morton offer no model that properly accounts for the costs and benefits associated with the transaction, including massive merger-specific efficiencies; properly credits the impact of contractual and reputational constraints on Illumina's post-merger behavior; and properly accounts for the ability of MCED test providers to take steps to reduce their reliance on Illumina. (RX3864 (Carlton Expert Report) ¶ 55.)

Response to Finding No. 811

[redacted]

[redacted]

[redacted]

812. [redacted]

Response to Finding No. 812

[redacted]

[redacted]

813. Complaint Counsel and Dr. Scott Morton have posited a future downstream market, but it fails to specify what that market will look like, what firms will compete in that market, and what will be the characteristics of the rivals' products. (RX3864 (Carlton Expert Report) ¶ 87.)

Response to Finding No. 813

[redacted]

814. Such facts are necessary in order to model the effect of any incentive to raise rivals' costs, but they are absent from Dr. Scott' Morton's analysis. (RX3864 (Carlton Expert Report) ¶ 87.)

Response to Finding No. 814

[redacted]

[redacted]

D. Complaint Counsel and Dr. Scott Morton Fail to Account for Illumina's Pre-Merger Stake in GRAIL and Make Unwarranted Assumptions in Describing the Alleged Changes in Illumina's Incentives

815. In an analysis of a vertical merger, it is important to compare the premerger world to the post-merger world to understand the impact of the merger on the merging parties' incentives. (RX6000 (Carlton Trial Dep. at 92–94).)

Response to Finding No. 815

[redacted]

816. Absent the Transaction, Illumina would have a 12% stake in GRAIL's profits and would receive 7% of GRAIL's net revenues on every sale. (PFF ¶ 50.)

Response to Finding No. 816

[redacted]

[redacted]

817. The royalty is a unique feature of GRAIL's contract with Illumina, reflecting Illumina's contributions to the formation of GRAIL—Illumina has no comparable arrangement with any other test developer purportedly developing an MCED test. (deSouza (Illumina) Tr. 2463–64; PX7107 (deSouza (Illumina) Dep. at 191); Strom (Morgan Stanley) Tr. 3543–44; RX6000 (Carlton Trial Dep. at 92–94).)

Response to Finding No. 817

The proposed finding is vague and misleading. It is unclear what "contributions to the formation of Grail" Respondents are referring to or what a "comparable arrangement" means. It is misleading because Illumina does offer a comparable arrangement for any company that signs the Open Offer. The standardized IVD partnership agreement in the Open Offer requires, for IVD rights to all platforms, a tech access fee of $25 million, development milestone payments of $1 million to $5 million per IVD test kit, and a revenue sharing royalty of six percent. (PX0087 at 021, 041 (Illumina IVD Test Kit Agreement – All Platforms, dated Mar. 30, 2021)). Therefore, this Court should disregard the proposed finding.

818. In light of the pre-merger royalty and equity stake, under Complaint Counsel's own theory of Illumina's incentives, Illumina "makes much more money if a customer uses the GRAIL test than if it uses that of" a GRAIL rival, which means "there already is an incentive to favor GRAIL" and "therefore, the merger" has no effect on Illumina's dealings with GRAIL rivals. (RX6000 (Carlton Trial Dep. at 93–94).)

Response to Finding No. 818

[redacted]

[redacted]

[redacted]

819. [redacted]

Response to Finding No. 819

[redacted]

[redacted]

820. Dr. Scott Morton purports to quantify Illumina's incentives before and after the transaction, but her only attempt at quantifying those incentives makes unwarranted assumptions and carries no weight:

Response to Finding No. 820

The proposed finding is conclusory, unsupported, incomplete, and inconsistent with the evidentiary record, which demonstrates that Dr. Scott Morton applied sound economic reasoning in her analysis of Illumina's changed incentives post-deal. The proposed finding cites no evidence to support its contention and should be disregarded for that reason alone. The proposed finding is vague and misleading to the extent it refers to unspecified "unwarranted assumptions," and to the extent it refers to Dr. Scott Morton's "only attempt" to quantify Illumina's incentives. Therefore, this Court should disregard the proposed finding.

820.1 [redacted]

[redacted]

Response to Finding No. 820.1

[redacted]

[redacted]

820.2 [redacted]

Response to Finding No. 820.2

[redacted]

820.3 [redacted]

Response to Finding No. 820.3

[redacted]

[redacted]

820.4 [redacted]

Response to Finding No. 820.4

[redacted]

[redacted]

820.5 [redacted]

Response to Finding No. 820.5

[redacted]

[redacted]

821. There is no basis for Professor Scott Morton's assumption that any rival MCED test developer would pay a royalty similar to GRAIL, and the assumption ignores the unique nature of the GRAIL royalty and the undisputed fact that no other supply agreement contains such a provision. (RX6000 (Carlton Trial Dep. at 92–94).)

Response to Finding No. 821

The proposed finding is incorrect. There is a basis for Dr. Scott Morton's assumption that rival MCED test developers would pay a royalty similar to Grail. Among other sources of evidence, Dr. Scott Morton relied on the standardized IVD partnership agreement in the Open Offer, which requires, for IVD rights to all platforms, a tech access fee of $25 million, development milestone payments of $1 million to $5 million per IVD test kit, and a revenue sharing royalty of six percent. (PX0087 at 021, 041 (Illumina IVD Test Kit Agreement – All Platforms, dated Mar. 30, 2021)). Moreover, Dr. Gao of Singlera testified that Illumina sent Singlera a draft IVD rights term sheet, which included a $40 per sample "Market Access Fee" (in

addition to other fees and a 10 percent revenue share). (PX7042 (Gao (Singlera) IHT at 78-80); *see* PX8516 (Singlera) at 006 (Singlera, Email attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020)). Therefore, this Court should disregard the proposed finding.

822. Correcting for the erroneous assumption that any rival MCED test developer would pay a royalty similar to GRAIL, the result of her analysis shows that there is an incentive to favor GRAIL in the world without the merger because Illumina makes much more money if a customer uses the GRAIL test than if it uses that of the hypothetical rivals in Professor Scott Morton's quantification analysis. That means, if Professor Scott Morton were right about Illumina having a post-merger incentive to favor GRAIL, it would have that incentive even without the merger. (RX6000 (Carlton Trial Dep. at 92–94); RX3864 (Carlton Expert Report) at ¶ 148, Table 4.)

Response to Finding No. 822

[redacted]

[redacted]

[redacted]

[redacted]

822.1 The table below shows the results of Dr. Scott Morton's quantification after correcting for her erroneous assumption:

[redacted]

(RX3864 (Carlton Expert Report) ¶ 148, Table 4.)

Response to Finding No. 822.1

[redacted]

[redacted]

[redacted]

822.2 The first row of Table 4 replicates the conclusions from Scott Morton Table 2. According to this hypothetical, pre-merger, Illumina makes similar profits from selling to GRAIL and selling to GRAIL's hypothetical rivals. The second row corrects the error on royalty rates; and the third row additionally corrects the error of relying on 2023 data. The third row demonstrates that, even pre-merger, Illumina makes approximately five times as much from selling a unit through GRAIL rather than through GRAIL's rivals. Therefore, any incentive to foreclose, by Dr. Scott Morton's reasoning, currently exists. (RX3864 (Carlton Expert Report) ¶ 149.)

Response to Finding No. 822.2

[redacted]

[redacted]

[redacted]

822.3 As Dr. Carlton put it: "if you believed those assumptions -- which I do not -- but if you correct for the fact that she has improperly excluded royalties from rival one and rival two, you find that in her -- with her assumptions, there already is an incentive to deal with GRAIL and not deal with the rivals, and, therefore, the merger would do nothing." (RX6000 (Carlton Trial Dep. at 92–94).)

Response to Finding No. 822.3

[redacted]

[redacted]

[redacted]

E. There is No Basis to Predict That Foreclosure Would Cause Material Diversion From Future MCED Tests to GRAIL

1. Diversion is a Necessary Condition for Foreclosure

823. Significant diversion is a necessary condition for a vertical merger to give rise to foreclosure incentives because, as a matter of basic economics, "if there's no diversion, then there's no incentive to engage in [a foreclosure] strategy because the vertically integrated firm would just lose sales" and therefore "you need significant diversion for the strategy to make sense." (RX6000 (Carlton Trial Dep. at 21–22).)

Response to Finding No. 823

The proposed finding is vague, incomplete, misleading, and conclusory. It is vague because the term "significant diversion" is not defined. There is no way to tell from the proposed finding or the source, Dr. Carlton's trial deposition testimony, how much diversion Dr. Carlton deems necessary to give rise to foreclosure incentives. The finding is incomplete because it does not describe any other factors besides diversion that factor into whether a vertical merger will create foreclosure incentives. It is conclusory because it provides no rationale for Dr. Carlton's contention other than to point out that "if there's no diversion, then there's no incentive to engage in [a foreclosure] strategy…" And it is misleading insofar as it suggests that Dr. Carlton has been able to conclude that there will not be "significant diversion" between Galleri and other MCED tests. Dr. Carlton testified only that he believes it is "unclear" whether Grail and other MCED tests will have high diversion ratios. (RX6000 (Carlton Trial Depo.) at

26-27). [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

824. [redacted]

Response to Finding No. 824

[redacted]

2. Relevance of Product Differentiation

825. Downstream harm from a raising-rivals-costs strategy can only occur if the downstream rivals' products are not too differentiated and, even then, only under specific circumstances. (RX3864 (Carlton Expert Report) ¶ 50.)

Response to Finding No. 825

The proposed finding is vague. [redacted] Therefore, this Court should disregard the proposed finding.

826. Dr. Carlton explained that "if products are very different from one another, it suggests that they're unlikely to be close substitutes, and if they're not close substitutes, then the diversion of sales from the rival -- to in this case GRAIL . . . [is] likely to be low or nonexistent", and "if it's low or nonexistent, then the incentive -- the profit incentive to engage in the raising rivals' cost strategy . . . will also be low or nonexistent". (RX6000 (Carlton Trial Dep. at 40–41); RX3864 (Carlton Expert Report) ¶ 50).)

Response to Finding No. 826

The proposed finding is vague and misleading. [redacted]

[redacted]

827. Illumina's incentive to raise rivals' costs is diminished the greater the downstream tests are different from each other, because the greater the differentiation is between GRAIL and its rivals, the less diversion would be expected to GRAIL if Illumina attempted to raise rivals' costs. (RX3697 (Carlton 2019) at 7–9; RX3864 (Carlton Expert Report) ¶ 87.)

Response to Finding No. 827

The proposed finding is incomplete and misleading insofar as it suggests that Illumina lacks the incentive to raise rivals' costs. [redacted]

[redacted]

828. [redacted]

Response to Finding No. 828

[redacted]

829. [redacted]

Response to Finding No. 829

[redacted]

[redacted]

3. **No Possibility of Current Diversion**

830. Galleri is the only NGS-based MCED test on the market. (*Supra* PFF ¶ 698.)

Response to Finding No. 830

[redacted]

[redacted]

[redacted]

[redacted]

831. Because Galleri is the only NGS-based MCED test on the market, there could be no sales from Galleri rivals to divert today – current diversion is impossible. (RX6000 (Carlton Trial Dep. at 46).)

Response to Finding No. 831

[redacted]

[redacted]

4. **No Basis To Predict Future Diversion Given Differentiation Of Galleri And Other Tests In Development**

832. There also is substantial uncertainty around the MCED tests in development. (*Supra* PFF ¶¶ 701–706).)

Response to Finding No. 832

[redacted]

[redacted]

[redacted]

833. There is no way to exactly know what the MCED tests-in-development will look like, if and when they are launched. (*Supra* PFF ¶¶ 680.1–680.5.)

Response to Finding No. 833

[redacted]

[redacted]

[redacted]

834. It is unfounded speculation to say that any MCED tests-in-development would include, at any point in the foreseeable future, features that could make them reasonably close substitutes for GRAIL's Galleri test. (*Supra* PFF ¶¶ 680.1–680.5.)

Response to Finding No. 834

[redacted]

[redacted]

[redacted]

[redacted]

835. Most of the MCED test developers cited by Complaint Counsel are planning to launch tests as single-cancer tests, with additional plans to incrementally add additional cancers to their tests at some point in the future. (*Supra* PFF ¶¶ 701–705.)

Response to Finding No. 835

[redacted]

836. None of the MCED test developers cited by Complaint Counsel have ascertained the specific features of any MCED test that they may launch in the future, although it is clear that none are on a path to launching a test, like Galleri, that can detect 50 cancer types and cancer of origin in a single blood draw:

Response to Finding No. 836

[redacted]

Moreover, the proposed finding is incomplete and misleading. There is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of trial, Galleri had been clinically shown to detect only seven types of early-stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); [redacted]

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer *early* detection test (2) for use in screening an asymptomatic population. [redacted] The fact that Galleri can detect

signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. [redacted] Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). The CCGA study did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. [redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of

50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021). Therefore, this Court should disregard the proposed finding.

836.1 [redacted]

Response to Finding No. 836.1

[redacted]

[redacted]

836.1.1 [redacted]

Response to Finding No. 836.1.1

[redacted]

[redacted]

836.1.2 [redacted]

Response to Finding No. 836.1.2

[redacted]

[redacted]

836.1.3 [redacted]

Response to Finding No. 836.1.3

[redacted]

[redacted]

[redacted]

836.2 [redacted]

Response to Finding No. 836.2

[redacted]

[redacted]

836.2.1 [redacted]

Response to Finding No. 836.2.1

[redacted]

[redacted]

[redacted]

836.2.2 [redacted]

Response to Finding No. 836.2.2

[redacted]

[redacted]

836.2.3 [redacted]

Response to Finding No. 836.2.3

[redacted]

[redacted]

[redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

836.3 [redacted]

Response to Finding No. 836.3

[redacted]

[redacted]

836.3.1 [redacted]

Response to Finding No. 836.3.1

[redacted]

[redacted]

[redacted]

836.3.2 [redacted]

Response to Finding No. 836.3.2

[redacted]

[redacted]

[redacted]

836.3.3 [redacted]

Response to Finding No. 836.3.3

[redacted]

836.4 [redacted]

Response to Finding No. 836.4

[redacted]

[redacted]

836.4.1 [redacted]

Response to Finding No. 836.4.1

[redacted]

[redacted]

836.4.2 [redacted]

Response to Finding No. 836.4.2

[redacted]

[redacted]

[redacted]

836.5 [redacted]

Response to Finding No. 836.5

[redacted]

[redacted]

[redacted]

[redacted]

836.5.1 [redacted]

Response to Finding No. 836.5.1

[redacted]

[redacted]

836.5.2 [redacted]

Response to Finding No. 836.5.2

[redacted]

[redacted]

[redacted]

836.5.3 [redacted]

Response to Finding No. 836.5.3

[redacted]

[redacted]

836.5.4 [redacted]

Response to Finding No. 836.5.4

[redacted]

[redacted]

837. Given the vast differences between those tests and Galleri, it is clear that they will be too dissimilar to permit a foreclosure strategy to divert material sales to Illumina from GRAIL rivals at any point in the foreseeable future. (*Supra* PFF ¶¶ 825–829.)

Response to Finding No. 837

[redacted]

838. A test that detects only colon cancer, or only lung and liver cancer, is not substitutable for a test that screens for more than 50 cancer types. (*Supra* PFF ¶ 687.)

Response to Finding No. 838

[redacted]

[redacted]

[redacted]

[redacted]

839. Number of cancers detected. Galleri differs from the MCED tests-in-development based on the numbers of cancers that can be detected.

Response to Finding No. 839

The proposed finding is unsupported by any evidence and should be disregarded. It is also misleading to the extent that it suggests that Galleri is able to screen for over 50 cancers. As explained in the Response to [redacted] below, Galleri has only been shown to screen for seven cancers in an asymptomatic population, whereas CancerSEEK, from Exact/Thrive, has been shown to screen for eight cancers in an asymptomatic population. [redacted] Therefore, the finding is misleading to the extent that it suggests there is a significant difference in the number of cancers that can be screened by Galleri compared to other MCED tests in development, and it is incorrect to the extent it suggests that Galleri has been proven to screen for more cancers in an asymptomatic population than any other MCED test. Therefore, this Court should disregard the proposed finding.

839.1 [redacted]

Response to Finding No. 839.1

[redacted]

[redacted]

[redacted]

839.2 [redacted]

Response to Finding No. 839.2

[redacted]

[redacted]

839.2.1 [redacted]

Response to Finding No. 839.2.1

[redacted]

[redacted]

839.3 [redacted]

Response to Finding No. 839.3

[redacted]

[redacted]

839.4 [redacted]

Response to Finding No. 839.4

[redacted]

[redacted]

[redacted]

839.5 [redacted]

Response to Finding No. 839.5

[redacted]

[redacted]

839.6 [redacted]

Response to Finding No. 839.6

[redacted]

[redacted]

[redacted]

839.6.1 [redacted]

Response to Finding No. 839.6.1

[redacted]

[redacted]

[redacted]

839.7 Exact/Thrive's data shows only that its CancerSEEK assay can detect whether a patient has one of 10 types of cancer (and is unable to identify which one without further invasive testing in the form of a PET-CT scan). [redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

Response to Finding No. 839.7

[redacted]

[redacted]

[redacted]

839.8 The published Singlera data is from a small, 418–sample case control study and shows only that Singlera's PanSeer assay potentially could detect five types of cancer. (RX3115 (Chen 2020) at 3.)

Response to Finding No. 839.8

The proposed finding is incorrect. Singlera has completed a proof-of-concept study of its PanSeer test in China on 100,000 people, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the development of the PanSeer MCED test and expects to launch it as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)). Therefore, this Court should disregard the proposed finding.

840. Number of tests performed. Galleri differs from the MCED tests-in-development based on the number of tests of which it is comprised, in that Galleri consists of a single blood draw, whereas some of the tests in development actually comprise a series of tests.

Response to Finding No. 840

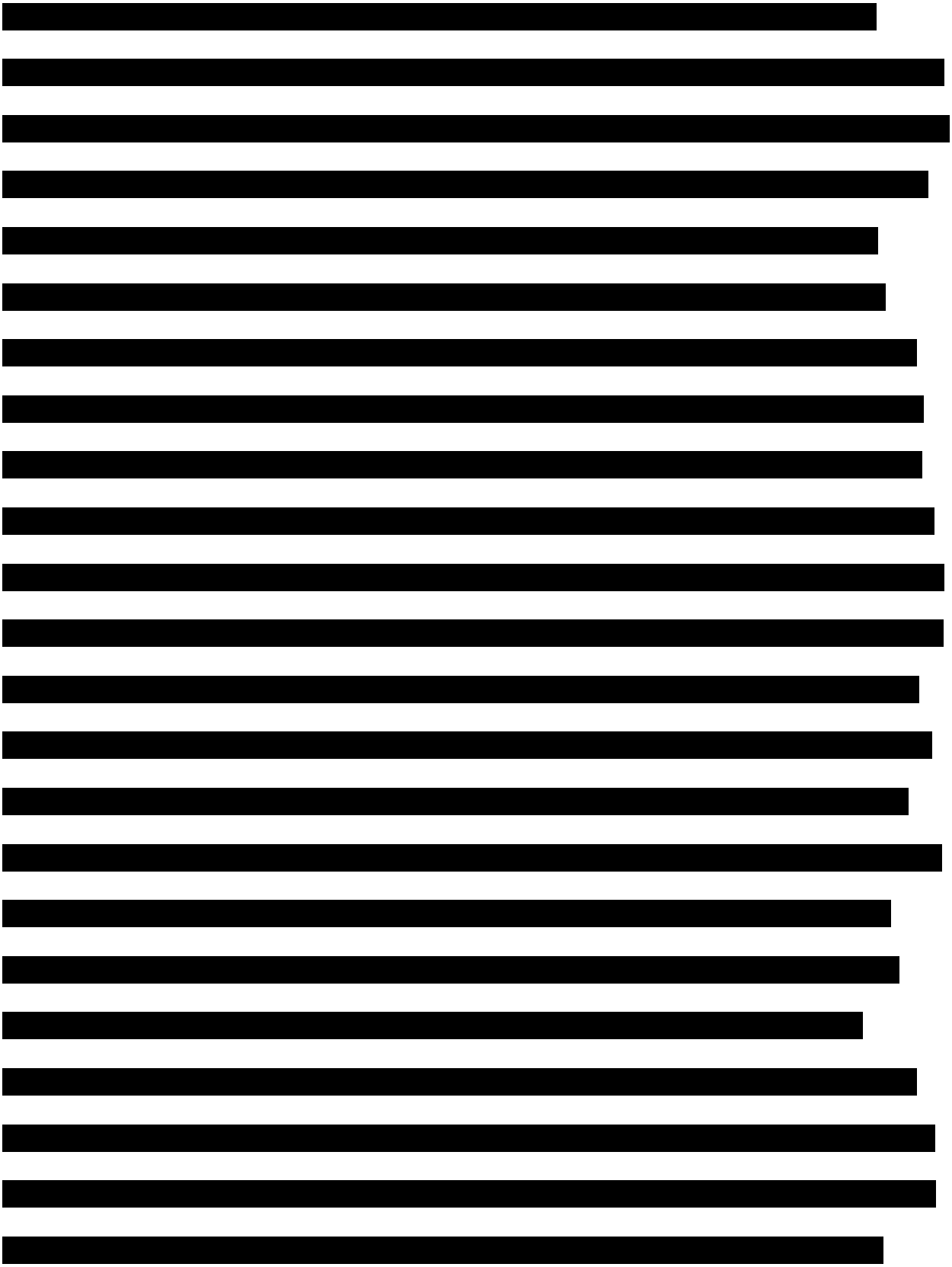
The proposed finding is unsupported by any evidence and should be disregarded. Because it does not contain a citation, it is not possible to verify the substance of the proposed finding. Furthermore, the proposed finding is vague because it does not define which "MCED tests-in-development" it is referring to or which tests "actually comprise a series of tests." Moreover, the weight of the evidence shows that Galleri will also need follow-up confirmation. Hans Bishop – Grail's former CEO – admitted at trial that there will need to be "diagnostic confirmation" of any positive diagnosis through either a tissue biopsy or through PET-CT scan. (Bishop (Grail) Tr. 1387). [redacted].

840.1 For example, Exact's CancerSEEK test is actually three separate tests in the form of its latest published trial: two blood draws and a PET-CT scan. (Lengauer (Exact/Thrive) Tr. 246–48.) [redacted]

Response to Finding No. 840.1

[redacted]

[redacted]



[redacted]

840.2 [redacted]

Response to Finding No. 840.2

[redacted]

[redacted]

[redacted]

840.3 [redacted]

Response to Finding No. 840.3

[redacted]

[redacted]

840.4 [redacted]

Response to Finding No. 840.4

[redacted]

[redacted]

Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

[redacted] If Grail had already established the extent to which PET-CT and other types of diagnostic testing would be required to achieve diagnostic resolution when Galleri is used in a real-world setting, such a study would not be necessary. Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). Therefore, this Court should disregard the proposed finding.

841. Cancer Signal of Origin. Galleri also differs from the MCED tests in development based on its ability to determine cancer signal of origin.

Response to Finding No. 841

[redacted]

[redacted]

[redacted]

[redacted]

841.1 Galleri is able to detect tissue of origin; that is, for positive cases, the test reveals where (lung, stomach, etc.) the detected cancer is likely located based on the same blood draw used to detect the cancer's presence. (*Supra* PFF ¶ 61.)

Response to Finding No. 841.1

The proposed finding is incomplete and misleading to the extent it suggests that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population.

The CCGA study did not involve a real-world population, but rather was a case-control study that involved individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Among other factors, some of the blood samples in CCGA were "collected from participants with cancer after biopsies had been carried out," which the authors note "could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." Galleri's reported tissue of origin accuracy was worse for Stage I-II cancers than for Stage III-IV cancers in CCGA (*See* RX3430 at 6, Figure 4 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation

Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2]). This fact suggests that Galleri's CSO performance will be worse in an asymptomatic screening population that does not include previously diagnosed Stage III and Stage IV cancer patients, as the CCGA study did.

The proposed finding is also misleading to the extent it suggests that Galleri's algorithmic cancer signal of origin prediction is capable of definitively localizing cancer "through liquid biopsy alone." [redacted] Additionally, a positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.)

[redacted] Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of

origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted] If Grail had already established the extent to which PET-CT and other types of diagnostic testing would be required to achieve diagnostic resolution when Galleri is used in a real-world setting, such a study would not be necessary. Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual

Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). [redacted]

Therefore, this Court should disregard the proposed finding.

841.2 No other MCED test-in-development has demonstrated this capability. (*Supra* PFF ¶ 684.2.)

Response to Finding No. 841.2

The proposed finding is vague because the phrase "this capability" is ambiguous and undefined; it is unclear what capability Respondents are referencing. The proposed finding should be disregarded for this reason alone.

[redacted]

The proposed finding is also incomplete and misleading to the extent it suggests that

Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population.

[redacted]

[redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Among other factors, some of the blood samples in CCGA were "collected from participants with cancer after biopsies had been carried out," which the authors note "could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." Galleri's reported tissue of origin accuracy was worse for Stage I-II cancers than for Stage III-IV cancers in CCGA (*See* RX3430 at 6, Figure 4 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2]). This fact suggests that Galleri's CSO performance will be worse in an asymptomatic screening population that does

not include previously diagnosed Stage III and Stage IV cancer patients, as the CCGA study did.

[redacted] Additionally, a positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.) Therefore, this Court should disregard the proposed finding.

> 841.3 For example, Thrive's CancerSEEK cannot detect tissue of origin and instead requires a diagnostic full-body PET-CT scan both to confirm the results of the blood testing—*i.e.*, that cancer has in fact been detected— and also to localize the potential cancer. (Lengauer (Exact/Thrive) Tr. 246–48.)

Response to Finding No. 841.3

[redacted]

[redacted]

The proposed finding is also incomplete and misleading to the extent it suggests that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population.

[redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Among other factors, some of the blood samples in CCGA were "collected from participants with cancer after biopsies had been carried out," which the authors note "could increase the possibility that the tumor cfDNA fraction may

increase relative to before the biopsy." Galleri's reported tissue of origin accuracy was worse for Stage I-II cancers than for Stage III-IV cancers in CCGA (*See* RX3430 at 6, Figure 4 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2]). This fact suggests that Galleri's CSO performance will be worse in an asymptomatic screening population that does not include previously diagnosed Stage III and Stage IV cancer patients, as the CCGA study did.

The proposed finding is incomplete and misleading to the extent that it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT.

[redacted]

841.4 Similarly, Singlera has said that any patient testing positive would then undergo additional blood testing and/or follow-up imaging to detect cancer signal of origin. (RX3115 (Chen 2020) at 6.)

Response to Finding No. 841.4

The proposed finding is misleading and incomplete. It cites a scientific article from 2020 with many authors, not just people representing Singlera. Singlera's CEO, Dr. Gao, testified at

trial that Singlera's PanSeer MCED test is designed to detect multiple cancer types, as well as "the origin of location." (Gao (Singlera) Tr. 2874).

[redacted]

A positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.)

Interim results from PATHFINDER, an actual interventional trial for Galleri, indicate that additional imaging testing was required for positive results 90 percent of the time. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting

Presentation, June 4, 2021) ("Most participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)."). Over half the positive results in PATHFINDER with diagnostic resolution were determined to be false positives (55.4%) and 25 percent of participants who received falsely positive results underwent at least one invasive procedure. (RX3041 at 004 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

[redacted]

841.5 [redacted]

Response to Finding No. 841.5

[redacted] Additionally, a positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002

(Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.).

[redacted]

841.6 [redacted]

Response to Finding No. 841.6

[redacted]

[redacted]

841.7 [redacted]

Response to Finding No. 841.7

[redacted]

[redacted]

Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

[redacted] If Grail had already established the extent to which PET-CT and other types of diagnostic testing would be required to achieve diagnostic resolution when Galleri is used in a real-world setting, such a study would not be necessary. Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). Therefore, this Court should disregard the proposed finding.

841.8 [redacted]

Response to Finding No. 841.8

[redacted]

The proposed finding is incomplete and misleading to the extent that it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT. [redacted]

[redacted]

841.9 [redacted]

Response to Finding No. 841.9

[redacted]

841.10 However, Dr. Abrams, the only expert primary care physician to testify in this case, explained that the ability to detect tissue of origin is a key differentiating feature that will influence physician and patient choice. (Abrams Tr. 3624.)

Response to Finding No. 841.10

The proposed finding is unreliable. In forming his opinions, Dr. Abrams did not consult any surveys of primary care physicians outside of his practice and did not rely on any specific

conversations with other physicians. (Abrams Tr. 3682). Dr. Abrams also did not conduct any surveys himself to obtain information about the importance of tissue of origin as a differentiating feature that may influence physician and patient choice. (Abrams Tr. 3682). [redacted] Therefore, Dr. Abrams' opinion related to this finding is unreliable and should be given little weight.

The proposed finding is incomplete and misleading to the extent that it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT. [redacted]

[redacted]

[redacted]

841.11 [redacted]

Response to Finding No. 841.11

[redacted]

The proposed finding is incomplete and misleading to the extent that it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT. [redacted]

[redacted]

[redacted]

841.12 [redacted]

Response to Finding No. 841.12

[redacted]

[redacted]

[redacted]

842. Sensitivity. Galleri differs from the MCED tests-in-development based on its degree of sensitivity, meaning how often a test correctly returns a positive result for an individual who has the cancer for which they are being screened. (*Supra* PFF ¶ 172.)

Response to Finding No. 842

[redacted]

[redacted]

Singlera's Taizhou study demonstrated the PanSeer has a sensitivity of "88 to 90 percent and [a] specificity of 96 percent" for the cancers used in the study. (Gao (Singlera) Tr. 2876). [redacted]

[redacted] The DETECT-A study established CancerSEEK's sensitivity was 52 percent, detecting double the number of cancers first detected by standard screening methods. (Lengauer (Third Rock Ventures) Tr. 168-69). [redacted]

The proposed finding is also incomplete and misleading to the extent that it suggests that Grail is able to claim today what the sensitivity of its MCED test will be in Galleri's intended use population (i.e. in an asymptomatic screening population). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Grail admits as much itself. [redacted]

[redacted]

842.1 [redacted]

Response to Finding No. 842.1

[redacted]

[redacted]

Singlera's Taizhou study demonstrated the PanSeer has a sensitivity of "88 to 90 percent and [a] specificity of 96 percent" for the cancers used in the study. (Gao (Singlera) Tr. 2876). [redacted] The DETECT-A study established CancerSEEK's sensitivity was 52 percent, detecting double the number of cancers first detected by standard screening methods. (Lengauer (Third Rock Ventures) Tr. 168-69). [redacted]

The proposed finding is also incomplete and misleading to the extent that it suggests that Grail is able to claim today what the sensitivity of its MCED test will be in Galleri's intended use

population (*i.e.* in an asymptomatic screening population). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Grail admits as much itself. [redacted]

[redacted]

842.2 [redacted]

Response to Finding No. 842.2

[redacted]

[redacted]

Singlera's Taizhou study demonstrated the PanSeer has a sensitivity of "88 to 90 percent and [a] specificity of 96 percent" for the cancers used in the study. (Gao (Singlera) Tr. 2876). [redacted] The DETECT-A study established CancerSEEK's sensitivity was 52 percent, detecting double the number of cancers first detected by standard screening methods. (Lengauer (Third Rock Ventures) Tr. 168-69). [redacted]

The proposed finding is also incomplete and misleading to the extent that it suggests that Grail is able to claim today what the sensitivity of its MCED test will be in Galleri's intended use population (i.e. in an asymptomatic screening population). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation

of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Grail admits as much itself. [redacted]

843. Specificity. Galleri also differs from the MCED tests in development based on its degree of specificity, meaning how often a test correctly returns a negative result for an individual who does not have the cancers for which they are being screened; the higher the specificity, the lower the false positive rate. (*Supra* PFF ¶ 173.)

Response to Finding No. 843

[redacted]

[redacted]

[redacted]

843.1 [redacted]

Response to Finding No. 843.1

[redacted]

[redacted]

843.2 Further, most of the tests-in-development are focused on cancers with existing standard-of-care screening protocols (*supra* PFF ¶¶ 482, 701–705), for which a high sensitivity is necessary but a lower specificity is acceptable given the ability to turn to standard-of-care screening to assess whether a positive case is a true positive. (Cote Tr. 3829.) As Dr. Cote explained:

> "[T]he requirements for a single cancer screening test, particularly one that has a standard of care screen that can be reflexed to . . . are very different from a multicancer screening test. What is

> really required . . . in the colorectal assay would be a high level of sensitivity, hopefully superior to that of the standard of care screening, which is a colonoscopy, and the lower level of specificity and the increase in the false-positive rate can be tolerated because the reflex here would be colonoscopy, which would be the direct visualization of the colon." (Cote Tr. 3829.)

Response to Finding No. 843.2

[redacted]

[redacted]

[redacted]

843.3 [redacted]

Response to Finding No. 843.3

[redacted]

[redacted]

[redacted]

[redacted]

843.4 As the table below also shows (*see supra* PFF Table 7), the specificity of the MCED tests-in-development to which Complaint Counsel points, for which there is any specificity information in the record, differ from specificities for the cancers detected by Galleri.

Table 7

Test	Galleri (GRAIL) 1 Blood Test	CancerSEEK (Exact/Thrive)			PanSeer (Singlera) 1 Blood Test
		1 Blood Test	2 Blood Tests	2 Blood + PET-CT	
Study	CCGA3	DETECT-A			Taizhou L.S.
Types of Cancer	50	10			5
Cancer Signal of Origin	Yes	No	No	Yes	No
Specificity	99.5%	95.3%	98.9%	99.6%	96.1%
Sensitivity	51.5%	30.2%	27.1%	15.6%	94.9%
PPV	44.4%	5.9%	19.4%	28.3%	

(RX3409 (Klein 2021); RX3419 (Lennon et al., 2020); RX3115 (Chen 2020).)

Response to Finding No. 843.4

The proposed finding misleading, incomplete, and against the weight of the evidence.

The proposed finding is misleading because the weight of the evidence shows that the CCGA

study is not indicative of Galleri's performance in the intended use (asymptomatic) population as explained below. Any attempt to directly compare the results in DETECT-A (an interventional study involving asymptomatic individuals) and Taizhou (an observational study involving asymptomatic individuals) with CCGA (a case-control study involving diagnosed cancer patients, including patients with Stage IV cancer) meaningless and inherently unreliable. They are fundamentally different types of studies. Dr. Ofman of Grail conceded that "[t]o find all 50 cancer types in a real-world population would require hundreds of thousands of people[.]" (RCFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298).

[redacted]

The authors of the CCGA-3 sub-study itself make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Accordingly, the proposed finding is misleading and unsupported to the extent that there is reliable evidence today of the combined sensitivity and specificity at which Grail will perform in an asymptomatic screening population.

To put the above points plainly, a case control study will tend to produce inflated performance results relative to how a test would performance in an asymptomatic screening population (the actual population in which MCED tests are intended to be used). Notwithstanding this, and notwithstanding the above admissions, Respondents nonetheless attempt to compare their case-control results to results from studies involving asymptomatic populations and pretend as if they are comparing apples to apples. They are not; the attempt

itself is inherently misleading.

[redacted]

[redacted]

843.5 [redacted]

Response to Finding No. 843.5

[redacted]

[redacted]

843.6 [redacted]

Response to Finding No. 843.6

[redacted]

[redacted]

[redacted]

844. The only medical experts called to testify agree that Galleri is very different from the MCED tests in development. (PX6097 (Abrams Expert Report) ¶ 42; Cote Tr. 3727, 3777–78, 3782–83.)

Response to Finding No. 844

The proposed finding is vague, misleading, and unreliable. It is vague because it does not elaborate on what "very different from the MCED tests in development" means or why that matters. It is misleading and unreliable because Dr. Cote is not a "medical expert," and his testimony deserves no weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report in violation of this Court's order; [redacted] Dr. Cote is also not qualified to provide expert opinion testimony about [redacted]

[redacted] Therefore, Dr. Cote's opinion related to this finding is unreliable and should be given little weight. In addition to Dr. Cote being unqualified and not credible, his opinion about the acceptability of certain features on an MCED test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

Moreover, the proposed finding is unreliable because, in forming his opinions, Dr. Abrams did not consult any surveys of primary care physicians outside of his practice and did not rely on any specific conversations with other physicians. (Abrams Tr. 3682). Dr. Abrams also did not conduct any surveys himself to obtain information about the importance of various MCED test features that may influence physician and patient choice. (Abrams Tr. 3682). Dr. Abrams is too biased and unqualified to opine on whether or how [redacted] Therefore, Dr. Abrams' opinion related to this finding is unreliable and should be given little weight. Therefore, this Court should disregard the proposed finding.

844.1 [redacted]

Response to Finding No. 844.1

[redacted]

[redacted]

[redacted]

[redacted]

844.2 Dr. Cote opined that other MCED tests in development would not be substitutes for Galleri, both because of their inability to detect cancer signal of origin, as well as other performance metrics such as sensitivity and specificity. (Cote Tr. 3727, 3777–78, 3782–83.)

Response to Finding No. 844.2

The proposed finding is vague, relies on improper expert opinion, incomplete, misleading, against the weight of the evidence. The proposed finding is vague because Dr. Cote is not an economist, and so it is unclear what he means by his use of the term "substitutes." It is vague because it does not specifically refer to any MCED tests in development, only "other" MCED tests. It also does not define what "other performance metrics" Dr. Cote may have been referring to. Further, it is misleading because [redacted]

The proposed finding relies on improper expert opinion. Dr. Cote is not qualified to provide expert opinion testimony about [redacted] Dr. Cote is also not qualified to provide expert opinion testimony about [redacted]

The proposed finding is against the weight of the evidence to the extent it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT. [redacted]

[redacted]

The proposed finding is also misleading to the extent it suggests that the performance of Galleri's algorithmic tissue of origin prediction feature has been clinically established in the intended use population for Galleri. [redacted]

[redacted] Additionally, a positive Galleri result "requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer," *notwithstanding* Galleri's "cancer signal of origin" feature. (PX0063 at 002 (Grail, https://grail.com/galleri/, accessed on Apr. 29, 2021). Indeed, Grail's CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387.)

The proposed finding is also incorrect that [redacted] Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

[redacted] Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects and exceeds his expertise; his trial testimony also contained unsupported claims about his experience related to

MCED test development that exceed the information disclosed in his report in violation of this Court's order; [redacted] Specifically, Dr. Cote is not qualified to provide expert opinion testimony about [redacted] Dr. Cote is also not qualified to provide expert opinion testimony about [redacted] For all the above reasons, this Court should disregard the proposed finding.

844.3 Dr. Cote testified:

[redacted]

[redacted]

Response to Finding No. 844.3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

845. [redacted]

Response to Finding No. 845

[redacted]

[redacted]

5. **No basis to predict limited-cancer tests will develop to close rivals to Galleri in foreseeable future.**

846. Expanding a single cancer test to a 50–cancer test is not a viable approach to developing a test like Galleri in the foreseeable future:

Response to Finding No. 846

The proposed finding is completely unsupported by evidence. This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). This proposed finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. It is also vague and misleading. It is unclear which single cancer test or 50-cancer test the finding is referring to, what a "test like Galleri" means, or what time frame the Respondents mean by "the foreseeable future." It is also misleading insofar as it suggests that Galleri, or a "test like Galleri," is a "50-cancer test." As

described elsewhere in Complaint Counsel's responses, Galleri has not demonstrated the ability to screen for 50 cancers in an asymptomatic population. [redacted]

> 846.1 As Dr. Aravanis explained, for each cancer included in an MCED like Galleri, the developer has "to go through a somewhat similar process to what GRAIL did", meaning "a research phase", "a test development phase", and "a clinical phase", and that must be done "for each cancer", which, if done "serially" would take a "very long time" and is "not practical". (Aravanis (Illumina) Tr. 1895–96.)

Response to Finding No. 846.1

The proposed finding is misleading to the extent it suggests that MCED test developers all must follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline. It also reflects self-serving testimony from an Illumina executive, Dr.

Aravanis. Dr. Aravanis's also does not have the foundation to testify as to other MCED test developers process.

[redacted]

[redacted]

846.2 Dr. Aravanis further explained that it is not "straightforward to expand [a single cancer test] to all other cancers" because **"**to develop a test for a new indication, like a new cancer, you have to go get samples related to that different cancer. You have to find the signals. Then you have to develop a technology for that. Then you have to do a -- the relevant clinical trial. There's no shortcut. . . . [T]here's hundreds of diagnostics developed" and "I've never heard of an example where because you developed a test for

one thing, you can now – it's a shortcut to develop a test for something different." (Aravanis (Illumina) Tr. 1901–02).

Response to Finding No. 846.2

The proposed finding is misleading to the extent it suggests that MCED test developers all must follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline, or that Dr. Aravanis knows about every way that such tests may be developed. It also reflects self-serving testimony from Dr. Aravanis, an Illumina executive. Dr. Aravanis also does not have the foundation to testify regarding the development process of other MCED developers.

[redacted]

[redacted]

[redacted]

846.3 Similarly, Dr. Cote testified that developing a single-cancer test does not put a test developer "in a position where they're ahead in developing a cancer screening test for a different cancer" because the "development of biomarkers for a particular cancer will not be adequate for other cancers" and, for each cancer, the developer must "go through the case-control verification to determine whether or not the assay has the performance characteristics needed for . . . the new target cancer, and then has to go through a prospective trial depending on which cancer is being targeted" – a process that can take years and with no certainty of a successful outcome. (Cote Tr. 3787.)

Response to Finding No. 846.3

The proposed finding is misleading to the extent it suggests that MCED test developers all must follow an identical, one-size-fits-all, artificial development and commercialization roadmap and timeline that Dr. Cote invented in his flawed analysis. Dr. Cote is also not qualified to provide expert opinion testimony about [redacted].

[redacted]

[redacted]

[redacted]

F. Complaint Counsel Failed to Account for the Impact Any Attempted Foreclosure would have on Illumina's NGS Sales and Reputation.

1. Illumina's Core Business Consists Of Selling NGS Instruments And Consumables.

847. Illumina's core business consists of selling NGS instruments and consumables. (*Supra* PFF ¶ 22.)

Response to Finding No. 847

The proposed finding is vague to the extent "core business" is undefined and ambiguous. The proposed finding is also unsupported and conclusory to the extent it cites only to Respondents' other proposed findings of fact. Therefore, this Court should disregard the proposed finding.

848. Illumina's NGS products comprise the vast majority (more than 90%) of its revenues and profits. (*Supra* PFF ¶ 22.)

Response to Finding No. 848

The proposed finding is unsupported and conclusory to the extent it cites only to Respondents' other proposed findings of fact. Moreover, nothing in the cited material speaks to

Illumina's profits. The proposed finding is also irrelevant. As explained in Complaint Counsel's post-trial briefing, notwithstanding the fact that MCED testing is a small percentage of Illumina's core business today, Illumina's pre-Acquisition ordinary course documents show that Illumina seeks to fundamentally evolve its business to shift to clinical services in the future. Therefore, this Court should disregard the proposed finding.

849. Illumina's NGS business is expected to be the dominant driver of Illumina's profits well into the future:

Response to Finding No. 849

The proposed finding is incomplete, and without evidentiary support. Additionally, the proposed finding is vague and ambiguous to the extent the phrases "dominant driver" and "well into the future" are undefined. The proposed finding is also irrelevant. [redacted] Therefore, this Court should disregard the proposed finding.

849.1 As Mr. deSouza explained, "[t]he vast majority of Illumina's revenue in the next ten years will come from our sequencing business, our sequencers and consumables." (deSouza (Illumina) Tr. 2291.) Because Illumina's "core business is to sell sequencers and consumables", its "strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve." (deSouza (Illumina) Tr. 2378.)

Response to Finding No. 849.1

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

849.2 Dr. Aravanis similarly testified that "Illumina's business is based on growing sequencing markets" by "lowering the cost, allowing people to do more sequencing" and "has also been driven by new applications that are developed", and "Illumina is hoping for more of those applications to be developed" on its platforms, which creates "a strong incentive for us to continue to decrease cost, and that's our plan." (Aravanis (Illumina) Tr. 1922.)

Response to Finding No. 849.2

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

849.3 Dr. Goswami testified that the majority of Illumina's revenues come from NGS tools, and the Transaction "keeps our commitment to delivering NGS solutions to the broad sector of customers we serve." (PX7087 (Goswami (Illumina) Dep. at 145–46).)

Response to Finding No. 849.3

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

850. Any attempt by Illumina to foreclose GRAIL's alleged rivals would harm Illumina's core NGS business, because it would result in the loss of highly profitable NGS sales in MCED and non-MCED applications. (deSouza (Illumina) Tr. 2378; [redacted], 86).)

Response to Finding No. 850

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

850.1 Those sales either would divert to rival sequencing platforms, such as those in active development described above, or they would dissipate because customers would respond to foreclosure by choosing to no longer invest in NGS applications on Illumina systems. (RX6000 (Carlton Trial Dep. at 33–37); deSouza (Illumina) Tr. 2380–81; Febbo (Illumina) Tr. 4331–32; [redacted] 86.)

Response to Finding No. 850.1

The proposed finding is vague, incomplete, and misleading. [redacted]

[redacted]

[redacted]

850.2 In either case, the loss to Illumina would be enormous – unless, contrary to fact, Illumina was assured of recouping a substantial volume of the resulting loss in profits through diversion to GRAIL. (RX3864 (Carlton Expert Report) ¶ 86.)

Response to Finding No. 850.2

The proposed finding is vague, incomplete, and misleading. It is vague because it is unclear what "in either case" means, or what an "enormous" loss or "recouping a substantial volume of the resulting loss" means. It misleading because [redacted]

It is also misleading because, [redacted] As Dr. Carlton noted in his report, [redacted]

[redacted]

[redacted]

850.3 As Mr. deSouza explained, "if we [raised prices] we would lose [our customers'] business. They would move on to . . . a BGI or a Thermo", that is, Illumina would lose upstream revenues it earns today and expects in the future both from MCED developers and other customers. (deSouza (Illumina) Tr. 2379–80.)

Response to Finding No. 850.3

The proposed finding is vague, incomplete, and misleading. It is vague because it does not specify what "other customers" Illumina may lose revenue from. It is misleading because Illumina need not raise prices to its customers across the board in order to raise prices (or otherwise foreclose) MCED test developers. Illumina has the ability to identify and discriminate against MCED test developers posing competitive threats to Grail's Galleri test. (*see* CCFF ¶¶ 2608-2701).

It is also misleading because, for MCED testing, Illumina is the only NGS sequencing provider that meets the requirements of MCED test developers. [redacted]

[redacted]

[redacted]

[redacted]

850.4 Dr. Febbo similarly confirmed that attempted foreclosure would "really disincentivize an R&D lab or clinical labs from using our platforms, which would have a major impact on our business" through lost NGS sales. (Febbo (Illumina) Tr. 4331–32.)

Response to Finding No. 850.4

The proposed finding is vague, incomplete, and misleading. It is vague because it does not specify what "R&D lab[s] or clinical labs" would be disincentivized from using Illumina platforms as a result of foreclosure of MCED test developers. It is misleading because Illumina need not raise prices to such customers in order to raise prices (or otherwise foreclose) MCED test developers. Illumina has the ability to identify and discriminate against MCED test developers posing competitive threats to Grail's Galleri test. (*see* CCFF ¶¶ 2608-2701).

It is also misleading because, for MCED testing, Illumina is the only NGS sequencing provider that meets the requirements of MCED test developers. [redacted]

[redacted]

[redacted]

[redacted]

851. [redacted]

Response to Finding No. 851

[redacted]

[redacted]

[redacted]

[redacted]

852. Dr. Scott Morton admitted that she did not quantify the per-test gross profits Illumina earns from selling sequencing products used by any hypothetical MCED rival for non-screening tests or the gross profits that Illumina would lose if, as a result of attempted foreclosure of an MCED test developer, the test developer moves all of its tests, including non-MCED tests, to a different platform. (RX3852 (Scott Morton Dep. at 242–44).)

Response to Finding No. 852

The proposed finding mischaracterizes Dr. Scott Morton's testimony. In the cited portion of the deposition transcript, Dr. Scott Morton did not admit to not quantifying and comparing gross profits earned by Illumina depending on whether it decides to foreclose Grail's rival MCED test developers. Nowhere on any of the cited pages does the transcript mention anything about quantification of gross profits or foreclosure of MCED test developers. The proposed finding should therefore be disregarded.

However, as discussed above, Illumina is the only NGS sequencing provider that meets the requirements of MCED test developers. [redacted]

[redacted]

2. **Any Attempted Foreclosure Would Inflict Significant Reputational Harm on Illumina.**

853. Illumina has cultivated a reputation as a trusted supplier of NGS technology. (*See* PX7101 (Vogelstein (Johns Hopkins) Dep. at 57–58) ("Illumina makes fantastic instruments. I mean, they are unbelievably good . . . it's amazing what they've done.").)

Response to Finding No. 853

The proposed finding is irrelevant. Illumina's ability to make quality sequencers is irrelevant as to whether its customers "trust" them. The proposed finding is also misleading insofar it conflates "trusted supplier" with customers' trust in Illumina to do anything other than what will make Illumina the most money possible. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted]. When acquiring Grail, Mr. deSouza told

Illumina's investors that the acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). As Complaint Counsel explains in its Post-Trial Reply Brief any reputational consequences will not mitigate Illumina's incentive to foreclose its rivals. First, Illumina already has a poor reputation among its customers; second, even if Illumina's reputation gets worse, it would have no impact on Illumina's upstream sales; and, third, Illumina insulated itself against any potential reputational damage through its Open Offer. (Complaint Counsel's Post-Trial Reply Brief at Section IV.).

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

[redacted]

Finally, Respondents have insulated themselves against any potential reputational damage by requiring *confidential* arbitration as the only enforcement mechanism for a breach of Illumina's commitments under the Open Offer. [redacted]

Therefore, this Court should disregard the proposed finding.

854. Illumina has developed its reputation by investing substantial amounts into innovation and dramatically lowering sequencing costs over time. (Aravanis (Illumina) Tr. 1922; (RX1100 (George (Invitae) Decl. ¶ 8).)

Response to Finding No. 854

The proposed finding is unsupported to the extent that neither of the cited sources make any reference to Illumina's general reputation in the market, or to any "substantial amounts" invested by Illumina. Complaint Counsel does not disagree that Illumina's reputation is that of the dominant provider of NGS services, and that the cost for gene sequencing has tended to decrease over time, particularly with the advent of NGS. (*See* CCFF ¶¶ 4-18; 892). The proposed finding is misleading, however, to the extent it implies that Illumina has a "good" reputation. To the contrary, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted]

[redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted] Therefore, this Court should disregard the proposed finding.

855. Today, Illumina's brand is synonymous with innovative, low-cost sequencing systems. (*See* Berry (Illumina) Tr. 811–12.)

Response to Finding No. 855

The proposed finding is incomplete and misleading. It is also supported only by the self-serving testimony of an Illumina executive who benefits from building up the supposed "brand" of her employer.

The proposed finding is misleading insofar it suggests that Illumina's "brand" is somehow incompatible with the company's goal of making the most money possible. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, Mr. deSouza told Illumina's investors that the acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶

3094). Accordingly, it does not make business sense for Illumina to sacrifice potential revenue for the sake of upholding its alleged reputation as a "trusted supplier of NGS technology." Indeed, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted] Therefore, this Court should disregard the proposed finding.

855.1 Since the release of its first Genome Analyzer instrument in 2007, Illumina has driven down sequencing costs from roughly $300,000 per gigabase to less

than $8 per gigabase today. (RX3515 (National Human Genome Research Institute Sequencing Costs Data) at 1; RX3864 (Carlton Expert Report) ¶ 77.)

Response to Finding No. 855.1

[redacted]

855.2 The phenomenon of dramatically declining sequencing costs is known in the industry as "Flatley's law", referring to Jay Flatley, Illumina's former CEO and Chairman. (*See* Berry (Illumina) Tr. 811–12 ("'Flatley's law' was a term coined by . . . a writer in Forbes magazine when he wrote an article comparing the reduction in the price of sequencing to Moore's law, which describes the reduction in the price of like silicon wafers or something in the computer industry, and [under Jay Flatley's] leadership where we really drove significant, significant reductions in the price of sequencing . . . down towards the level that they are today.").)

Response to Finding No. 855.2

The proposed finding is incomplete and misleading. It is also supported only by the self-serving testimony of an Illumina executive who benefits from building up the supposed "brand"

of her employer. Moreover, nothing about "Flatley's law" suggests that Illumina has passed on all reductions in the cost of sequencing to its customers. Because "more than 90% of the world's sequencing data is generated using Illumina NGS technology," Illumina can decide whether to lower its prices to customers commensurate with any reductions in sequencing costs that it achieves or decide to take higher profits. (CCFF ¶ 1020). [redacted]

The proposed finding is misleading insofar it suggests that "Flatley's law" is somehow incompatible with the company's goal of making the most money possible. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, Mr. deSouza told Illumina's investors that the acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it does not make business sense for Illumina to sacrifice potential revenue for the sake of upholding its alleged reputation as a "trusted supplier of NGS technology." Indeed, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr.

2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted] Therefore, this Court should disregard the proposed finding.

855.3 Reductions in sequencing costs have encouraged the development of entire industries that would not otherwise exist and for which Illumina is the primary supplier of sequencing inputs. (RX3864 (Carlton Expert Report) ¶ 77.)

Response to Finding No. 855.3

[redacted]

[redacted]

856. Both Illumina witnesses and third parties attested to Illumina's long-standing reputation for innovation and driving down sequencing costs.

Response to Finding No. 856

The proposed finding is completely unsupported by evidence and should be disregarded. It is also vague to the extent the terms "long-standing," "reputation," and "innovation" are undefined. Moreover, this unsupported contention is against the weight of the evidence as explained in Complaint Counsel's briefing.

856.1 In a sworn declaration to the FTC, an Illumina oncology customer (Invitae) stated that "Illumina's role as an innovator in NGS has moved the field forward tremendously, as they have constantly and steadily reduced sequencing costs over time." (RX1100 (George (Invitae) Decl. ¶ 8).)

Response to Finding No. 856.1

The proposed finding is incomplete and misleading. Nothing about the cited quote suggests that Illumina has passed on all reductions in the cost of sequencing to its customers. Because "more than 90% of the world's sequencing data is generated using Illumina NGS technology," Illumina can decide whether to lower its prices to customers commensurate with any reductions in sequencing costs that it achieves or decide to take higher profits. (CCFF ¶ 1020). [redacted]

The proposed finding is misleading insofar it suggests that "Illumina's role as an innovator" is somehow incompatible with the company's goal of making the most money

possible. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, Mr. deSouza told Illumina's investors that the acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it does not make business sense for Illumina to sacrifice potential revenue for the sake of upholding its alleged reputation as a "trusted supplier of NGS technology." Indeed, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

856.2 Gary Gao of Singlera testified that Singlera is "very happy Illumina has paved the way for NGS" and that he credited "the Illumina team for leading a genome revolution". (PX7102 (Gao (Singlera) Dep. at 70).)

Response to Finding No. 856.2

The proposed finding is irrelevant as to whether Illumina will have the ability and incentive to foreclose Grail's rivals. Illumina can both build a good NGS sequencer and have the ability and incentive to foreclose Grail's rivals. The proposed finding is incomplete and misleading insofar as it suggests that Dr. Gao is completely satisfied in his dealings with Illumina. Dr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

The proposed finding is also misleading because Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, Mr. deSouza told Illumina's investors that the acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it does not make

business sense for Illumina to sacrifice potential revenue for the sake of upholding its alleged reputation as a "trusted supplier of NGS technology." Indeed, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted] Therefore, this Court should disregard the proposed finding.

856.3 Ms. Berry explained that Illumina routinely measures its reputation using "net promoter score" customer surveys, a widely-used survey methodology, and frequently receives "very high Net Promoter Scores relative to industry benchmarks." (Berry (Illumina) Tr. 837–38.)

Response to Finding No. 856.3

The proposed finding is vague, incomplete, and misleading. It is vague because it is unclear what "net promoter score" customer surveys are or what is contained in such surveys. The significance of "very high Net Promoter Scores relative to industry benchmarks" is also unclear from the cited quote. The proposed finding is also supported only by the self-serving testimony of an Illumina executive who benefits from building up the supposed "brand" of her employer.

The proposed finding is misleading because Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, Mr. deSouza told Illumina's investors that the acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it does not make business sense for Illumina to sacrifice potential revenue for the sake of upholding its alleged reputation as a "trusted supplier of NGS technology." Indeed, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

Moreover, the weight of the evidence shows that Illumina's reputation among its

customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted] Therefore, this Court should disregard the proposed finding.

857. Illumina's reputation for NGS innovation and lowering sequencing costs is critical to the continued success of its NGS business and overall profitability:

Response to Finding No. 857

The proposed finding is completely unsupported by evidence and should be disregarded. It is also vague to the extent the terms "reputation," and "critical to the continued success" are undefined. Moreover, Respondents' unsupported contention is against the weight of the evidence for all the reasons explained in Complaint Counsel's post-trial briefing.

857.1 Illumina's profits from clinical applications are largely in the future. (S*ee* deSouza (Illumina) Tr. 2326–27 ("even with all the progress we've made in the last . . . almost two decades since the first human genome, today we still understand very little of how your genome translates into health and disease states. . . . There is a lot of research going on in that area, and once the researchers uncover the connections between your genome and those conditions, we'll start to see clinical applications emerge to do the testing based on that finding. . . . [W]e have so much undiscovered in front of us. As we discover that, I have no doubt we will see a lot more clinical applications emerge in the future."); Aravanis (Illumina) Tr. 1842–43 (NGS is still in the "early days" as a "tool for clinical diagnostics", and there are "many new applications emerging, and some of those

could be even bigger than the ones we have today"—it is "still early in seeing how [NGS] can benefit medicine.").)

Response to Finding No. 857.1

The proposed finding is incomplete and misleading. [redacted]

[redacted]

857.2 Illumina relies on its customers to invest in costly R&D to generate demand for Illumina's products, including in applications that have not yet been developed or possibly even conceived, creating a future stream of sequencing sales and profits. (*See, e.g.*, Berry (Illumina) Tr. 811 ("Our mission remains to . . . enable all attributes of our technology to drive accessibility and utilization across as many use cases as possible, and certainly pricing is a key element of that, a key enabler of that, and so continuing to drive down the price of sequencing is something that we are absolutely relentlessly continuing to pursue."); [redacted]

Response to Finding No. 857.2

[redacted]

[redacted]

[redacted]

857.3 To realize those future profits, Illumina must incentivize customers to invest, which requires that Illumina maintain its reputation as a supporter of innovation by its customers in products that use Illumina's NGS technology. (RX6000 (Carlton Trial Dep. at 33–35, 186, 188).)

Response to Finding No. 857.3

The proposed finding is vague, incomplete, and misleading. It is vague because it does

not define "those future profits" or specify which "customers" it is referring to. The proposed finding is incomplete and misleading because it does not account for the change in Illumina's incentives after acquiring Grail. Illumina spun out Grail "to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible." (PX2561 (Illumina) at 017 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, attaching "DRAFT Sands Investor Talking Points," Oct. 30, 2020); deSouza (Illumina) Tr. 2204-5).

Moreover, the proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the

Open Offer in subtle ways that will likely go undetected. [redacted]

857.4 [redacted]

Response to Finding No. 857.4

[redacted]

857.5 Illumina cannot predict which of its customers will create the next breakthrough product that will greatly expand the adoption of NGS. (RX6000 (Carlton Trial Dep. at 33–35, 186, 188).)

Response to Finding No. 857.5

The proposed finding is vague, incomplete, and misleading. It is vague because it does not define "breakthrough product" or what it means to "greatly expand the adoption of NGS." It is incomplete and misleading to the extent that it is referring to MCED test developers because it does not account for the change in Illumina's incentives after acquiring Grail. Illumina spun out Grail "to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible." (PX2561 (Illumina) at 017 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, attaching "DRAFT Sands Investor Talking Points," Oct. 30, 2020); deSouza (Illumina) Tr. 2204-5). [redacted]

[redacted]

Moreover, the proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

[redacted]

857.6 The future uses for Illumina's sequencing inputs are unknown and future demand for Illumina's sequencing inputs depends on downstream firms' willingness to invest in costly and uncertain R&D efforts using the Illumina sequencing platforms. [redacted]; PX7065 (Aravanis (Illumina) IHT at 143–44); [redacted]

Response to Finding No. 857.6

[redacted]

[redacted]

857.7 Illumina thus has the incentive to support all of its customers even where foreclosure could theoretically result in short term gain. (RX6000 (Carlton Trial Dep. at 33–35, 186, 188).)

Response to Finding No. 857.7

The proposed finding is vague, incomplete, and misleading. It is vague because it does not define "short term gain." It is incomplete and misleading to the extent that it is referring to MCED test developers because it does not account for the change in Illumina's incentives after acquiring Grail. Illumina spun out Grail "to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible." (PX2561 (Illumina) at 017 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, attaching "DRAFT Sands Investor Talking Points," Oct. 30, 2020); deSouza (Illumina) Tr. 2204-5). [redacted]

[redacted]

Moreover, the proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

857.8 [redacted]

Response to Finding No. 857.8

[redacted]

858. If Illumina attempted to foreclose cancer screening test developers, its reputation would change from a supporter of clinical development on its platforms to a supplier willing to engage in opportunistic hold-up when the applications it encourages customers to develop reach scale and profitability. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; [redacted]

Response to Finding No. 858

[redacted]

[redacted]

[redacted]

[redacted]

859. Such a reputation would damage Illumina's NGS business and its expectation of future profits from the expansion of NGS-based clinical testing. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; deSouza (Illumina) Tr. 2379–80.)

Response to Finding No. 859

The proposed finding is incomplete, misleading, and against the weight of the evidence. The proposed finding is also vague as "such a reputation" is undefined. It also relies on the self-serving testimony of Illumina executives, Dr. Aravanis, Dr. Febbo, and Mr. deSouza, who benefit from claiming that their employer has a reputation as a supporter of clinical development.

The proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Moreover, the weight of the evidence shows that Illumina's reputation among its

customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, the proposed finding is incomplete and misleading because Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

860. Many innovators would choose not to invest in developing emerging and future applications using Illumina's platforms—not just limited to cancer screening—opting instead to pursue such applications on rival upstream platforms, or not at all. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; deSouza (Illumina) Tr. 2379–80; [redacted]

Response to Finding No. 860

[redacted]

[redacted]

[redacted]

861. This in turn would stunt the growth and expansion of Illumina's NGS products to new applications and diminish Illumina's future sales in markets in which GRAIL is not active, making recoupment of those lost sales impossible. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; deSouza (Illumina) Tr. 2379–80; [redacted]

Response to Finding No. 861

[redacted]

[redacted]

[redacted]

[redacted]

862. Raising price to disadvantage clinical oncology test developers would thus substantially harm the growth of Illumina's core business. (RX3864 (Carlton Expert Report) ¶ 86).

Response to Finding No. 862

[redacted]

[redacted]

863. The reputational damage from an attempted foreclosure strategy would also harm Illumina by making it difficult to attract and retain the best scientists and innovators. (Aravanis (Illumina) Tr. 1922–23, 1931–32 (explaining that "many employees come to Illumina because of our culture and our values" and "impeding innovation would be counter to that" and make it difficult to "retain[] the talent we have and attract[] new people who want to work on developing new sequencing technology applications.").)

Response to Finding No. 863

The proposed finding is vague, incomplete, misleading, and against the weight of the evidence. It is vague because it does not describe what Illumina's "culture" and "values" are. It is unclear why an attempted foreclosure strategy against Grail's MCED rivals would result in the inability to retain and attract top talent, particularly if that talent is not even aware of such a strategy. It also relies on the self-serving testimony of an Illumina executive, Dr. Aravanis, who benefits from claiming that his employer has a reputation as a supporter of clinical development.

The proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

[redacted]

[redacted]

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted]

[redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, the proposed finding is incomplete and misleading because Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

864. Illumina's witnesses offered uncontested evidence an attempted foreclosure strategy would harm Illumina's reputation and, in turn, Illumina's future NGS growth and profitability:

Response to Finding No. 864

[redacted]

[redacted]

The proposed finding is also incorrect regarding the "uncontested" evidence about harm to Illumina's reputation. Substantial evidence has been submitted showing that Illumina may not suffer any harm to its reputation from a foreclosure strategy. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

[redacted]

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, [redacted].

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted] Singlera's

Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore, this Court should disregard the proposed finding.

> 864.1 As Dr. Aravanis explained, attempting to foreclose a GRAIL rival "would be very detrimental" because "our business is based on customers using our platforms for their applications, developing new applications" and "[w]ere we to do something like foreclose on a customer's business . . . we would jeopardize the existing customer relationships", and "at a kind of reputational level, to do something like that . . . is not consistent with our mission and values." (Aravanis (Illumina) Tr. 1922–23; 1931–32.)

Response to Finding No. 864.1

The proposed finding is vague, incomplete, misleading, and against the weight of the evidence. It is vague because it does not describe Illumina's "mission" or "values" and why they would prevent them from doing something if it was a way to maximize profits. It also relies on the self-serving testimony of an Illumina executives, Dr. Aravanis, who benefit from claiming that his employer has a reputation as a supporter of clinical development.

The proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

[redacted]

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted]

[redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, the proposed finding is incomplete and misleading because Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

> 864.2 Dr. Febbo explained: "[I]f we were to behave in a way that precluded competition or in a way that disincentivized groups to use our sequencing [in] screening, that would disincentivize other companies, laboratories from early research and development through the development of clinical tests from using our platform and, thus, it is in our best interest to make sure that we continue to create an environment where laboratories are excited to use our platform to develop screening tests for cancer, as well as all the other applications we see happening." (Febbo (Illumina) Tr. 4331–32.)

Response to Finding No. 864.2

The proposed finding is vague, incomplete, misleading, and against the weight of the evidence. It is vague because it does not describe what it means to "behave in a way that precluded competition" or "create an environment where laboratories are excited to use our platform." As discussed below, MCED test developers are required to use Illumina's platforms

for their tests, whether they are excited to do so or not. The finding also relies on the self-serving testimony of an Illumina executive, Dr. Febbo, who benefits from claiming that his employer has a reputation as a supporter of clinical development.

The proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Moreover, the weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted]

[redacted] Illumina's customers agree. [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, the proposed finding is incomplete and misleading because Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to,

among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

> 864.3 Mr. deSouza explained: "[I]f people heard that we were raising costs in a market, I mean, that would cause us to have a ripple effect of losses in our sequencer business, not just in the cancer screening market, not just in the oncology market, but across our customer base as a whole." (deSouza (Illumina) Tr. 2386–87) Mr. deSouza further noted that the reason it is "very important for us that our customers . . . recognize that we are the company that drives the cost of sequencing down at high quality and makes sequencing more accessible" is because we would lose their business. They would move on to, you know, a BGI or a Thermo", and for Illumina it is important to remain known as the company "that drives prices down" and "encourages an ecosystem even in markets where we have a test." (deSouza (Illumina) Tr. 2379–80.)

Response to Finding No. 864.3

The proposed finding is vague, incomplete, misleading, and against the weight of the evidence. It is vague because it does not specify which customers Illumina may lose revenue from. It is misleading because Illumina need not raise costs for its customers across the board in order to raise costs (or otherwise foreclose) MCED test developers. Illumina has the ability to identify and discriminate against MCED test developers posing competitive threats to Grail's Galleri test. [redacted] It also relies on the self-serving testimony of an Illumina executive, Mr. deSouza, who benefits from claiming that his employer has a reputation as a supporter of clinical development.

It is also misleading because, for MCED testing, Illumina is the only NGS sequencing provider that meets the requirements of MCED test developers. [redacted]

[redacted]

The proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Moreover, the weight of the evidence shows that Illumina's reputation among its

customers is poor. [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, the proposed finding is incomplete and misleading because Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

865. Complaint Counsel suggested that Illumina's reputation is not valuable to Illumina because, in its SEC disclosures, Illumina noted that its decision to close the Transaction could have potentially adverse consequences to Illumina's reputation; however, Mr. deSouza explained that, although there was *a risk* of reputational harm that had to be disclosed, Illumina believed that "once people hear what we did . . . there won't be damage to our reputation" given the reasons for closing and the impact of the Transaction on cancer care and saving lives. (deSouza (Illumina) Tr. 2236–37, 2340.)

Response to Finding No. 865

The proposed finding is vague, internally inconsistent, confusing, and misleading. Mr. deSouza claims that Illumina has been "very transparent with investors, you know, with our customers about, you know, why we – why we felt we had to do what we did." (deSouza (Illumina) Tr. 2340). Yet, despite this supposed transparency, Mr. deSouza reported to the SEC a risk of reputational harm from closing the transaction over the standstill obligation of the European Commission. He defended this action after the fact by saying that there will not actually be damage to Illumina's reputation "once people hear what we did." These actions and statements are at odds with each other. Mr. deSouza was either not transparent with his investors and customers, not forthright with the SEC in disclosing a risk of reputational harm, or not forthright with this Court when he said that he does not believe there will be damage to Illumina's reputation. If Mr. deSouza was transparent with investors and customers, then they

would already know "what Illumina did," and, according to Mr. deSouza, would support Illumina's decision to close the Transaction. Thus, there would be no need to mention a risk of reputational harm to the SEC. But Illumina did so anyway, illustrating that Illumina is willing to proceed with actions that it perceives as beneficial regardless of the potential for others (such as their customers) to disagree. It is unclear what else Mr. deSouza had in mind to notify "people" of "what Illumina did" so that those "people" would not perceive Illumina to have done something that is inconsistent with Illumina's "mission and values." [redacted]

The proposed finding is incomplete and misleading insofar as it assumes that any actions that Illumina takes to foreclose Grail's MCED test developer rivals will have a negative impact on its reputation. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Moreover, the weight of the evidence shows that Illumina's reputation among its

customers is poor. [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted] Therefore,

this Court should disregard the proposed finding.

> 865.1 In other words, Mr. deSouza, and Illumina, believe that closing the Transaction will *in fact* have a positive impact on Illumina's reputation. (deSouza (Illumina) Tr. 2236–37, 2340.)

Response to Finding No. 865.1

The proposed finding is vague, internally inconsistent, confusing, and misleading. If Mr. deSouza, and Illumina, believe that closing the Transaction will have a positive impact on Illumina's reputation, then it is unclear why they would include a risk of reputational harm in the SEC disclosure. In other words, it is unclear why Illumina and Mr. deSouza would indicate a potential risk to investors in a regulatory filing but tell this Court that they in fact thought the opposite – that there would actually be a benefit to Illumina's reputation. Further, to the extent that Illumina and Mr. deSouza believed that closing the transaction posed a risk to their reputation, it is unclear *why* they believed it would pose such a risk. Based on Mr. deSouza's testimony at trial, he appears to believe that "people" would initially consider it to be inconsistent with Illumina's "mission and values" to ignore the obligations placed on it by a governmental entity. But, according to Mr. deSouza, once those "people" realized that the Grail transaction is "really important," they would change their mind and think the opposite. (deSouza (Illumina) Tr. 2340). It is unclear why such "people" would change their minds when informed of the "importance" of the Transaction. Therefore, this Court should disregard the proposed finding.

> 865.2 There is nothing in the SEC disclosure that suggests that closing the Transaction would harm Illumina's reputation for lowering costs and innovating to encourage development on its platforms. (deSouza (Illumina) Tr. 2236–37, 2340.)

Response to Finding No. 865.2

The proposed finding is incorrect. There is a statement in the SEC disclosure that lists one of the "[i]mportant risk factors" of closing the Transaction as "the possibility of other

adverse consequences to, among other things, Illumina's reputation…" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021)). This suggests that closing the Transaction could harm Illumina's reputation. The SEC disclosure does not specify what Illumina's reputation is, but multiple Illumina executives testified that they believe that Illumina has a reputation for lowering costs and innovating to encourage development on its platforms. [redacted] Therefore, if Illumina's executives are correct about Illumina's reputation (and many MCED customers believe that they are not), then the SEC disclosure clearly contains a statement suggesting that its reputation would be harmed by closing the Transaction. This Court should disregard the proposed finding.

866. From an economic perspective, it is critical to consider a firm's reputation in analyzing that firm's incentives and ability to foreclose its customers following vertical integration. (RX6000 (Carlton Trial Dep. at 25).)

Response to Finding No. 866

The proposed finding is vague, incomplete, and misleading. It is vague because it is unclear what Respondents mean by "from an economic perspective." The proposed finding is misleading and incomplete because, as discussed above, reputational concerns matter more to some firms than others. Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

It is also misleading because if firms are unaware that Illumina is foreclosing on rivals, then Illumina will not suffer any reputational harm. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008).

Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

866.1 [redacted]

Response to Finding No. 866.1

[redacted]

[redacted]

866.2 Illumina's reputation constrains its incentive and ability to foreclose any GRAIL rival, because Illumina's customers are "investing large amounts of money right now in the hopes of having profitable products in the future", but "[i]f Illumina got a reputation for either jacking up price when someone's successful or harming them in some other way, that would have implications for the willingness of customers to continue to do business with Illumina as they're doing now." (RX6000 (Carlton Trial Dep. at 33–34).)

Response to Finding No. 866.2

The proposed finding is misleading and incomplete. The proposed finding is misleading to the extent it suggests that Illumina's customers have alternative sequencing alternatives on which to develop its products. As explained extensively in Complaint Counsel's post-trial briefing, for many applications that is simply not true. Further, to the extent that customers do become aware of Illumina's actions, Illumina may only develop a reputation as a company that disadvantages companies once they start competing with them, which is a reputation that Illumina has already developed among customers in the therapy selection and NIPT spaces. (*see* CCFF ¶¶ 3749-4164). For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

It is misleading because if firms are unaware that Illumina is foreclosing on rivals, then Illumina will not suffer any reputational harm. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina

can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

> 866.3 If Illumina "did start raising rivals' costs, its reputation for doing that would become known, and Illumina's customers now, as well as future customers, would be reluctant to do business with Illumina because they wouldn't want to make these huge investments if they think that Illumina is going to take advantage of them in the future". (RX6000 (Carlton Trial Dep. at 33–34).)

Response to Finding No. 866.3

The proposed finding is misleading. It is far from certain that Illumina's reputation for raising rivals' costs would become known. As explained below, because of the secretive terms of the Open Offer, it is possible for Illumina to foreclose Grail's rivals without anything becoming public. Moreover, not all Illumina customers also compete directly with Illumina, and customers that do not compete directly with Illumina have less reason to be concerned that Illumina will foreclose them. Other recent examples of Illumina attempting to foreclose rivals have come in the therapy selection and NIPT spaces, where Illumina was a supplier of all customers but then entered the downstream market as a competitor. (*see* CCFF ¶¶ 3749-4164).

It is misleading because if firms are unaware that Illumina is foreclosing on rivals, then Illumina will not suffer any reputational harm. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must

submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore,

this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

> 866.4 "Illumina's strategy of having customers who are inventing new uses for Illumina's NGS technology would be upended, and that would have negative consequences for Illumina and its profits." (RX6000 (Carlton Trial Dep. at 33–34).)

Response to Finding No. 866.4

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." See Order on Post-Trial Findings at 3. Here Respondents cite Dr. Carlton as the only source for the fact that Illumina has a "strategy of having customers who are inventing new uses for Illumina's NGS technology" in contravention of this Court's Order. This Court should disregard this evidence. The proposed finding is misleading and incomplete because Illumina can take action to foreclose Grail's rivals without other customers finding out, and customers would continue to invent new uses for Illumina's NGS technology because, for many applications, Illumina is the only viable choice of sequencing provider.

It is misleading because if firms are unaware that Illumina is foreclosing on rivals, then Illumina will not suffer any reputational harm. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

[redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

867. Illumina thus has an incentive to continue to innovate and reduce sequencing costs for customers who will discover clinical applications for Illumina's sequencers, not just in clinical oncology but in other areas as well. (RX3864 (Carlton Expert Report) ¶ 79).)

Response to Finding No. 867

[redacted]

[redacted]

3. **No Offsetting Advantage to Foreclosure.**

868. [redacted]

Response to Finding No. 868

[redacted]

[redacted]

[redacted]

869. As Mr. deSouza explained, "the testing business for many, many years will not have a profit, will lose business, and that's very typical in clinical testing businesses". (deSouza (Illumina) Tr. at 2386.)

Response to Finding No. 869

[redacted]

[redacted]

870. [redacted]

Response to Finding No. 870

[redacted]

[redacted]

871. It is only "after 2026" that Illumina gets "its first dollar of profit" from GRAIL, but "it's not until 2030 where we've recouped the losses we've made in GRAIL", and therefore, "about the next decade even, we really need and are really fueled by the profit pools associated with our sequencers." (deSouza (Illumina) Tr. 2383.)

Response to Finding No. 871

[redacted]

[redacted]

872. Thus, the uncontested evidence shows that Illumina's NGS business will remain its core business and will account for most of its profits for "many, many years". (deSouza (Illumina) Tr. at 2386.)

Response to Finding No. 872

The proposed finding is incorrect, vague, misleading, and incomplete. It is incorrect

because this evidence is not uncontested. [redacted] It is vague because it does not define the term "core business" or the duration of "many, many years." It is also based on self-serving testimony from Mr. deSouza, an Illumina executive who benefits from downplaying Illumina's incentive to foreclose Grail's competitors.

[redacted]

[redacted]

4. **No Evidence Illumina Can Target a Foreclosure Strategy to Avoid Upstream Losses.**

873. Although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.)

Response to Finding No. 873

The proposed finding is unsupported by the record. Nothing in the cited portion of the transcript mentions that Illumina, "in many cases," does not know what specific tests are in its customers' development pipeline. However, the finding suggests that, at least sometimes, Illumina does know what specific tests are in its customers' development pipeline.

Further, the proposed finding is incomplete, misleading, and against the weight of the evidence. It is misleading and incomplete because Illumina learns about its customers' development plans from a variety of sources as explained throughout Complaint Counsel's post-trial briefing. As an example, Illumina learns about its customers' products and development plans from conversations that it has with its customers. [redacted] For example, Ms. Berry admitted at trial that Illumina identifies many customers that are buying its products for the purpose of developing or performing oncology tests through sales and service interactions

with customers. (Berry (Illumina) Tr. 657-58). Illumina also examines customers' product developments when it negotiates supply agreements and offers prices to customers. [redacted] During supply agreement negotiations with [redacted] Illumina also learns about its customers products and development plans from public information. [redacted] Illumina identifies many of its customers that are buying its products for the purpose of developing or performing oncology tests through public information. (Berry (Illumina) Tr. 655-56). For example, Illumina reviews company websites and regulatory filings to gather this information. (Berry (Illumina) Tr. 655-56). [redacted] Therefore, this Court should disregard the proposed finding.

> 873.1 For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

Response to Finding No. 873.1

The proposed finding is unsupported and unreliable, and it should be disregarded. It cites to Respondents' witness, Dr. Carlton, for multiple factual assertions that are properly within the purview of fact witnesses. It is impermissible for Dr. Carlton to testify to whether he is aware that "many of the MCED tests Complaint Counsel claims are in development are unknown to

Illumina even today – much less their specific attributes…" Further, the proposed finding is vague because it does not define which MCED tests in development are supposedly unknown to Illumina.

Further, the proposed finding is incomplete, misleading, and against the weight of the evidence. It is misleading and incomplete because Illumina learns about its customers' development plans from a variety of sources. Illumina learns about its customers' products and development plans from conversations that it has with its customers. [redacted] For example, Ms. Berry admitted at trial that Illumina identifies many customers that are buying its products for the purpose of developing or performing oncology tests through sales and service interactions with customers. (Berry (Illumina) Tr. 657-58). Illumina also examines customers' product developments when it negotiates supply agreements and offers prices to customers. [redacted] During supply agreement negotiations with [redacted] Illumina also learns about its customers products and development plans from public information. [redacted] Illumina identifies many of its customers that are buying its products for the purpose of developing or performing oncology tests through public information. (Berry (Illumina) Tr. 655-56). For example, Illumina reviews company websites and regulatory filings to gather this information. (Berry (Illumina) Tr. 655-56). [redacted]

[redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

874. [redacted]

Response to Finding No. 874

[redacted]

875. Moreover, Illumina's instruments and consumables are multi-use products that can be and often are used by Illumina customers for a variety of sequencing applications. (*Supra* PFF ¶¶ 6–11.)

Response to Finding No. 875

The proposed finding is unsupported to the extent it makes no citation to the record, only to Respondents' other proposed findings of fact. The proposed finding is also vague and ambiguous because the terms "multi-use products" and "sequencing applications" are undefined. The proposed finding is also irrelevant as to whether Respondents would have the ability and incentive to foreclose Grail's rivals post-Aquisition. Therefore, this Court should disregard the proposed finding.

> 875.1 For example, Illumina markets its NovaSeq instrument and consumables, which are used by GRAIL for developing its early-detection tests, as "[f]lexibl[e] for virtually any genome, sequencing method, and scale of project". (RX2557 (Illumina) at 1.)

Response to Finding No. 875.1

The proposed finding is incomplete and misleading. Illumina designs and offers products tailored for customers to use in certain applications, including providing custom kits not just for specific applications, but also for specific customers. [redacted] For example, [redacted] Ms. Berry explained that Illumina offers "12 to 15 different kit configurations" for its NovaSeq sequencing instrument, so that it offers enough variety in reagents for "performance attributes that may be important to a particular customer." (Berry (Illumina) Tr. 827). Moreover, Ms. Berry admitted at trial that Illumina sells custom library kits to its NGS sequencing customers. (Berry (Illumina) Tr. 928 (stating that Illumina "sell[s] some very specific SKUs that . . . are absolutely marketed and designed for customers to, you know, specify their own specific content that they want to interrogate" and that "we [Illumina] will make a product specific to a customer's request")). This testimony is consistent with testimony from third parties, such as Guardant. Guardant's Bill Getty testified that Illumina provides Guardant with "customization and optimization of our

reagents." (PX7105 (Getty (Guardant) Dep. at 60-62)). Therefore, this Court should disregard the proposed finding.

876. If, hypothetically, Illumina were to cut off service to an instrument as Complaint Counsel speculates, that action could impact a range of tests (commercialized and in development), resulting in upstream losses without offsetting downstream gains from diversion. (RX6000 (Carlton Trial Dep. at 26–27).)

Response to Finding No. 876

[redacted]

877. Moreover, even if Illumina hypothetically could target a particular MCED test in development, news of Illumina's opportunistic conduct would reduce future sales to a range of

applications, not just the targeted MCED test. (RX3864 (Carlton Rep.) ¶ 49); RX6000 (Carlton Trial Dep.) at 33–34).)

Response to Finding No. 877

The proposed finding is vague, misleading, and incomplete. It is vague because it is not clear what the "range of applications" is that Respondents are referring to. It is misleading and incomplete because Illumina can take action to foreclose Grail's rivals without other customers finding out, and customers would continue to invent new uses for Illumina's NGS technology because, for many applications, Illumina is the only viable choice of sequencing provider.

It is misleading because if firms are unaware that Illumina is foreclosing on rivals, then Illumina will not suffer any reputational harm. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted]

[redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

877.1 As Mr. deSouza observed:

> "[I]f we were to raise prices on GRAIL, we would lose a lot more in sequencing business from the other markets. . . . The rest of our customers, whether they are in cancer detection or cancer at all, would look at what we did here and would be concerned about us doing that in the other markets that they're in. And so there would be a knock-on effect where we would lose sequencing business across our 7000 other customers who would be concerned about that kind of behavior. And so we wouldn't do that because, again, the much bigger part of our business is the sequencer business. So losses there really are much more impactful."
>
> (deSouza (Illumina) Tr. 2381–82.)

Response to Finding No. 877.1

The proposed finding is vague, misleading, and incomplete. It is vague because it is unclear what a "knock-on effect" is or which of Illumina's "7000 other customers" they would expect to lost business from. It is also based on self-serving testimony from Mr. deSouza, an Illumina executive who benefits from downplaying Illumina's incentive to foreclose Grail's

competitors. It is misleading because Illumina's customers that are not also competing with Illumina in downstream applications are unlikely to be "concerned about [Illumina] doing that in the other markets that they're in." Finally, the proposed finding is misleading and incomplete because Illumina can take action to foreclose Grail's rivals without other customers finding out, and customers would continue to invent new uses for Illumina's NGS technology because, for many applications, Illumina is the only viable choice of sequencing provider.

The proposed finding is misleading because if firms are unaware that Illumina is foreclosing on rivals, then Illumina will not suffer any reputational harm. For example, if customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (*see* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Additionally, the proposed finding is misleading because Illumina's reputation matters less for MCED test developers because MCED customers have nowhere else to go. [redacted]

[redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore, this Court should disregard the proposed finding.

878. Complaint Counsel's foreclosure theory does not take these real-world constraints into account. [redacted]

Response to Finding No. 878

[redacted]

[redacted]

G. NGS Costs Will be a Very Small Part of Future MCED Test Revenues and Profits.

1. Relevance of Upstream Input Costs Relative to Downstream Margins and Revenues.

879. One factor influencing the ability to successfully carry out a RRC strategy—and thus the incentive to engage in it—is the importance of an upstream firm's input costs to downstream rivals. (RX3864 (Carlton Expert Report) ¶ 62).

Response to Finding No. 879

The proposed finding is vague because it does not define what is meant by "influencing," "successfully carry out a RRC strategy," "importance," or "input costs." Moreover, the proposed finding is confusing because there is neither an explanation for when "input costs" would be "important[t]" nor how such costs "influenc[e]" a "RRC strategy."

The proposed finding is unsupported to the extent it makes a factual claim about Illumina's relationship as a supplier to Grail's rivals. No factual evidence is cited for the fact that "the importance of an upstream firm's input costs to downstream rivals" is a "factor influencing the ability to successfully carry out a RRC strategy" "and thus the incentive to engage in it." Moreover, this Court ordered that experts shall not be cited to "support factual

propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Carlton's expert report as the only source of evidence supporting this fact in contravention of this Court's order. The Court should disregard this evidence.

The proposed finding is also irrelevant. The correct question for assessing the ability to harm competition is not the percentage of an upstream product's costs relative to downstream competitors' profit, but rather whether the upstream product is a competitively significant input for the downstream market. As Complaint Counsel has explained extensively in its post-trial briefing, MCED test developers are dependent on Illumina's NGS platform.

The proposed finding is misleading and incomplete because it suggests that lower NGS prices to Grail's rivals somehow impairs Illumina's ability to harm them. The weight of the evidence contradicts Respondents' suggestion. Rather, it is clear that Illumina would have many tools at its disposal to harm Grail's rivals, including but not limited to charging relatively higher prices to rivals compared to Grail. [redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

880. There is "a very close relationship" between the prices a vertically integrated firm charges a rival for an input and the firm's incentive and ability to foreclose because "that ability is going to depend on the importance of cost in the downstream firm's reliance on" the upstream firm. (RX6000 (Carlton Trial Dep.) at 28.)

Response to Finding No. 880

The proposed finding is vague to the extent it does not define "relationship," "foreclose," "importance of cost" and "reliance on the upstream firm." The proposed finding is also confusing because it is unclear what is meant by "very close relationship" between price and the upstream firm's ability and incentive to foreclose. In addition, this Court ordered that experts

shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. The proposed finding is unsupported to the extent it purports to present as fact what the relationship is between NGS costs and Illumina's ability and incentive to harm Grail's rivals, as Dr. Carlton does in his full quoted testimony. (RX6000 (Calrton Trial Dep. at 28)) (noting that "ability is going to depend on the importance of cost in the downstream firm's reliance on in this case Illumina"). Here Respondents cite to the self-serving testimony of their own economic expert, Dr. Carlton, testimony as the only source of evidence supporting this fact in contravention of this Court's order. The Court should disregard this evidence.

The proposed finding is misleading and incomplete to the extent insofar as it states lower input costs implicate the upstream firm's ability to foreclose downstream competition. The unit price of a critical input is irrelevant to the upstream firm's ability to foreclose downstream rivals. In this case, regardless of what the price of sequencing is relative to MCED revenue, the weight of the evidence is clear that Illumina will have the ability to harm Grail's rivals by withholding, or offering inferior terms for, its NGS platform for which MCED test developers have no alternatives. [redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

881. If input costs are a small number today, or expected to be a small number in during the relevant time frame for the vertical analysis, it means the upstream firm will not have the ability to impose a large cost increase on a downstream rival because the cost increase would have to be substantial. (RX6000 (Carlton Trial Dep.) at 28–29.)

Response to Finding No. 881

The proposed finding is vague because it does not define "input costs," "small number," "relevant time frame for the vertical analysis," "large cost increase" or "substantial." It is also confusing because it presents a hypothetical situation with vague assumptions. The proposed

finding should be disregarded to the extent that the hypothetical situation described makes a factual claim as to Illumina's ability to foreclose or offer inferior terms to Grail's rivals. This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite to the self-serving testimony of their own economic expert, Dr. Carlton, as the only source of evidence supporting the proposed fact in contravention of this Court's Order.

The proposed finding is also misleading and incomplete. It disregards the fact that an upstream firm that faces no competition, such as Illumina, could nevertheless impose a substantial price increase on downstream rivals of Grail, or it could decide to engage in myriad other behaviors to disadvantage the downstream rivals—withholding or delaying access to new technology, reducing the quality of service, denying access to information and licenses necessary for FDA approval and commercialization, and sharing competitively sensitive information with Grail. The proposed finding also adopts a myopic focus on price-related harms when Complaint Counsel has alleged and shown that Illumina has a myriad of non-price related levers that Respondents can use to disadvantage Grail's rivals post-Acquisition**.** [redacted] In any event, the hypothetical posed by the proposed finding—and any suggestion that it illustrates the dynamics between Illumina and Grail's rivals—is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

882. If downstream margins are big enough, an input price increase could be absorbed by reducing downstream rivals' profits, rather than raising downstream price. This would result in no harm to consumers and, also, no diversion to GRAIL. (RX3864 (Carlton Expert Report) ¶ 62, n.181.)

Response to Finding No. 882

The proposed finding is vague because it does not define "big enough," "harm to consumers," and "diversion."

The proposed finding is unsupported insofar as it makes a factual claim about Illumina's relationship as a supplier to Grail's rivals. No factual evidence is cited. Moreover, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here, Respondents cite Dr. Carlton's expert report as the only source of evidence supporting this fact in contravention of this Court's order. The Court should disregard this evidence.

The proposed finding is also irrelevant. The correct question for assessing the ability to harm competition is not the percentage of an upstream product's costs relative to downstream competitors' profit, but rather whether the upstream product is a competitively significant input for the downstream market. As Complaint Counsel has explained extensively in its post-trial briefing, MCED test developers are dependent on Illumina's NGS platform.

The proposed finding is also misleading and incomplete. Dr. Carlton, in his direct testimony on this point, noted that the downstream firm might also pass on increased input prices to consumers. (RX6000 (Carlton Trial Dep. at 28-29)). In addition, there are other ways harming downstream rivals could impact competition aside from passing along increased input prices to consumers. The downstream firm might reduce its product quality in response, or it might have less ability to innovate to create better or more cost-effective products. Moreover, the proposed finding focuses on price increases to downstream rivals.

The proposed finding is also misleading and incomplete insofar as it disregards the fact that an upstream firm that faces no competition could nevertheless impose a substantial price

increase on downstream rivals, or it could decide to engage in myriad other behaviors to disadvantage the downstream rivals, including complete foreclosure. In any event, the hypothetical posed by the proposed finding—and any suggestion that it illustrates the dynamics between Illumina and Grail's rivals—is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

883. In a case where input costs are, or are projected to be, a small share of downstream revenues, that alone shows that "there are real constraints on the ability" of the upstream firm to foreclose downstream rivals. (RX6000 (Carlton Trial Dep. at 28–30).)

Response to Finding No. 883

The proposed finding is vague because it does not define "projected," "small share," "downstream revenues," "real constraints," or "foreclose."

The proposed finding is unsupported to the extent that it makes a factual claim about Illumina's relationship as a supplier to Grail's rivals. No factual evidence is cited. Moreover, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite the self-serving testimony of their own economic expert, Dr. Carlton, as the only source of evidence supporting this fact in contravention of this Court's order. The Court should disregard this evidence.

The proposed finding is also irrelevant. The correct question for assessing the ability to harm competition is not the percentage of an upstream product's costs relative to downstream competitors' profit, but rather whether the upstream product is a competitively significant input for the downstream market. As Complaint Counsel has explained extensively in its post-trial briefing, MCED test developers are dependent on Illumina's NGS platform.

The proposed finding is also misleading and incomplete. It draws an inference from the price charged to downstream firms that, without additional context, is inappropriate. In any event, the hypothetical posed by the proposed finding—and any suggestion that it illustrates the dynamics between Illumina and Grail's rivals—is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946..

2. **Evidence of projected Illumina NGS costs relative to projected downstream MCED revenues and margins.**

884. The only evidence in the record on NGS costs as a percentage of future downstream MCED revenues and margins shows that NGS costs will be a very small percentage of MCED test revenues and margins in the future. (RX6000 (Carlton Trial Dep.) at 30–31.)

Response to Finding No. 884

The proposed finding is vague because it does not define "NGS costs," "future downstream MCED revenues and margins," "very small percentage" and "in the future." The vagueness of the terms, including what constitutes "a very small percentage" without additional context or any factual support make this proposed finding confusing and unreliable.

The proposed finding is unsupported to the extent it relies on self-serving expert testimony to make a conclusory factual statement about what is in the record. No factual evidence is cited. Moreover, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite the self-serving testimony of their own economic expert, Dr. Carlton, as the only source of evidence supporting this fact in contravention of this Court's order. The Court should disregard this evidence.

The proposed finding is misleading and incomplete to the extent it purports to make an

unsupported conclusory statement about what evidence is in the record and its implications for Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. To the extent the finding suggests anything about the dynamics between Illumina and Grail's rivals, it is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

885. The only evidence of projected future NGS costs in the record is from Illumina's [redacted]

Response to Finding No. 885

[redacted]

a. Illumina.

886. [redacted]

Response to Finding No. 886

[redacted]

[redacted]

887. [redacted]

Response to Finding No. 887

[redacted]

888.

Response to Finding No. 888

888.1

Response to Finding No. 888.1

[redacted]

[redacted]

888.2 [redacted]

Response to Finding No. 888.2

[redacted]

[redacted]

888.3 Illumina's technological improvements are expected to drive significant reductions in Illumina input costs for GRAIL and any rival, and, even in the absence of those improvements, GRAIL and any rival, can improve the sequencing efficiency of their tests, reducing their reliance on Illumina inputs. (RX3864 (Carlton Expert Report) ¶ 70.)

Response to Finding No. 888.3

[redacted]

The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins—and the ability to "improve the sequencing efficacy" of MCED testing—is irrelevant for whether Illumina will have the ability and incentive

to harm Grail's rivals: Illumina still provides a critical input for MCED testing, for which there are no alternatives. [redacted]

888.4 The projected improvements in the number of reads per flow cell reduce the cost per test of Illumina's inputs for test developers and underpin Illumina's commitment to reduce sequencing costs per gigabase made available to customers by at least 43 percent by 2025. (PX7104 (Aravanis (Illumina) Dep. at 218–19); [redacted]

Response to Finding No. 888.4

[redacted]

[redacted]

[redacted]

888.5 [redacted]

Response to Finding No. 888.5

[redacted]

[redacted]

888.6 [redacted]

Response to Finding No. 888.6

[redacted]

[redacted]

888.7 [redacted]

Response to Finding No. 888.7

[redacted]

[redacted]

888.8 As Dr. Aravanis explained: "it became clear to the leadership at GRAIL and the R&D team that we were quickly approaching a point where sequencing cost would be immaterial. In fact, things like the blood tube would end up being more expensive . . . ." (PX7104 (Aravanis (Illumina) Dep. at 205–06); [redacted])

Response to Finding No. 888.8

[redacted]

[redacted]

889. [redacted]

Response to Finding No. 889

[redacted]

[redacted]

890. [redacted]

Response to Finding No. 890

[redacted]

[redacted]

[redacted]

891. At the time of the Illumina deal model, GRAIL paid Illumina approximately $135 per test, which the deal model projects will fall by ~80% in 2023 when V3 of Galleri is released, which will allow GRAIL to run five times as many samples per flow cell. (PX4091 (GRAIL) at -016).

Response to Finding No. 891

The proposed finding is vague to the extent "the time of the Illumina deal model" is undefined. The proposed finding is vague because it does not define "deal model," "V3 of Galleri," or "released." It is also confusing to the extent it does not identify how a "deal model" projects any prices Grail paid to Illumina per test. The proposed finding is unsupported to the extent it contains no citation to the deal model, or any other support for the claimed forthcoming drop in Grail's per-test payments to Illumina. [redacted] The proposed finding is misleading to the extent it depends on the significant unsupported assumption that the price of Illumina flow cells will remain constant even as the need for them decreases. (*See* PX7104 (Aravanis (Illumina) Dep. at 203–05 (noting that talking about the number of samples that can be put on a flow cell tells you nothing if you don't take into account the price of the flow cell)).

[redacted]

[redacted]

892. Illumina's supply contracts commit to reducing the price of Illumina's instruments and consumables by 43% by 2025. (PX0064 (Illumina) §5.d.)

Response to Finding No. 892

The proposed finding is vague because it does not define "supply contracts," "commit," or "price of Illumina's instruments and consumables."

The proposed finding is misleading to the extent it implies that reducing the price of sequencing by at least 43 percent meaningful to customers. [redacted] And, internally, [redacted] A price decrease from $600 to $100 would be an 83 percent decrease, much higher than 43 percent. (Berry (Illumina) Tr. 715). [redacted]

[redacted]

The proposed finding is also incomplete and misleading to the extent it implies that there will, in fact, be a price decrease of 43 percent to MCED customers. Specifically, the proposed finding is incomplete because Respondents omit that the 43 percent discount is only off the price per gigabase of sequencing, and it is misleading because a reduction in price per gigabase is irrelevant to MCED test developers. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)). Respondents use "price per gigabase" instead of price per read which is the most appropriate measure of price for liquid biopsy MCED tests. The ability to read one gigabase is equal to one billion nucleotides. [redacted] And, according to Illumina's own internal sequencing cost calculator, simply because the price *per gigabase* decreases does not mean that the price *per read* will also decrease. [redacted]

[redacted]

The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

893. [redacted]

Response to Finding No. 893

[redacted]

[redacted]

894. [redacted]

Response to Finding No. 894

[redacted]

[redacted]

895. [redacted]

Response to Finding No. 895

[redacted]

[redacted]

[redacted]

896. [redacted]

Response to Finding No. 896

[redacted]

[redacted]

896.1 [redacted]

Response to Finding No. 896.1

[redacted]

[redacted]

[redacted]

897. [redacted]

Response to Finding No. 897

[redacted]

[redacted]

898. [redacted]

Response to Finding No. 898

[redacted]

[redacted]

899. To the extent that any GRAIL rival emerges and has similar costs and test prices to GRAIL and [redacted], Illumina would need to raise price to GRAIL's rivals by a large amount for a RRC strategy to have significant impact. (RX3864 (Carlton Expert Report) ¶ 65.)

Response to Finding No. 899

[redacted]

900. To the extent that any GRAIL rival has comparable sequencing efficiency to GRAIL, Illumina input costs are not likely to be an important determinant of downstream profits. (RX3864 (Carlton Expert Report) ¶ 70.)

Response to Finding No. 900

The proposed finding is vague because it does not define "comparable sequencing efficiency," "input costs," "important determinant," or "downstream profits."

The proposed finding is unsupported because it relies on Respondents' own expert report for a factual proposition. No factual evidence is cited. Moreover, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite the self-serving report of their own economic expert, Dr. Carlton, as the only source of evidence supporting this fact in contravention of this Court's order. The Court should disregard this evidence.

The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

901. [redacted]

Response to Finding No. 901

[redacted]

[redacted]

902. Consistent with the documentary evidence from the internal business documents, Dr. Aravanis explained that sequencing costs will continue to "decrease over time" as a percentage of Galleri's costs due to GRAIL "innovations that will lead to a decreased usage of sequencing over time," which by itself, would reduce the amount of cost associated with sequencing per test," and in addition, "Illumina is also going to lower the cost of sequencing over time," as will "other sequencing providers", which will "compound the overall reduction in sequencing costs as a fraction of the test." (Aravanis (Illumina) Tr. 1924–25.)

Response to Finding No. 902

[redacted]

[redacted]

[redacted]

903. Mr. deSouza similarly explained that, "today sequencing costs represent about 10 percent of the price of Galleri" and "[b]y 2025, we project that sequencing costs will be less than 4 percent of the price of GRAIL's Galleri test." (deSouza (Illumina) Tr. 2388.)

Response to Finding No. 903

The proposed finding is vague because it does not define "sequencing costs," "price of Galleri," or "project."

The proposed is unsupported to the extent it seeks to implicate the sequencing costs of any of Grail's rivals. The finding relies solely upon the self-serving testimony of Illumina's CEO, Mr. deSouza, to describe Grail's sequencing costs. The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

b. [redacted]

904. [redacted]

Response to Finding No. 904

[redacted]

[redacted]

[redacted]

904.1 [redacted]

Response to Finding No. 904.1

[redacted]

[redacted]

904.2 [redacted]

Response to Finding No. 904.2

[redacted]

[redacted]

904.3 [redacted]

Response to Finding No. 904.3

[redacted]

[redacted]

904.4 [redacted]

Response to Finding No. 904.4

[redacted]

[redacted]

904.5 [redacted]

Response to Finding No. 904.5

[redacted]

[redacted]

904.6 [redacted]

Response to Finding No. 904.6

[redacted]

[redacted]

[redacted]

904.7 [redacted]

Response to Finding No. 904.7

[redacted]

[redacted]

904.8 [redacted]

Response to Finding No. 904.8

[redacted]

[redacted]

[redacted]

904.9 [redacted]

Response to Finding No. 904.9

[redacted]

[redacted]

904.10 [redacted]

Response to Finding No. 904.10

[redacted]

[redacted]

904.11 [redacted]

Response to Finding No. 904.11

[redacted]

[redacted]

[redacted]

905. [redacted]

Response to Finding No. 905

[redacted]

[redacted]

906. [redacted]

Response to Finding No. 906

[redacted]

[redacted]

907. [redacted]

Response to Finding No. 907

[redacted]

[redacted]

[redacted]

908. [redacted]

Response to Finding No. 908

[redacted]

[redacted]

3. **Significance Of Illumina's Declining NGS Costs And NGS Innovation.**

909. [redacted]

Response to Finding No. 909

[redacted]

[redacted]

910. [redacted]

[redacted]

Response to Finding No. 910

[redacted]

[redacted]

[redacted]

910.1 For example, Mr. deSouza explained that Illumina "will continue to see profit pool[s] in the sequencer business, but we believe that because of the competition in this business, the profit pools will -- the operating margin will decline over the years. And so . . . because of the competition, we expect a decline in the profit pools associated with sequencers, although it will continue to be a profitable business." (deSouza (Illumina) Tr. 2385.)

Response to Finding No. 910.1

The proposed finding is vague because it does not define "profit pool," "sequencer business," "competition," "operating margin," "expect," "decline," or "profitable business."

The proposed finding—which relies on self-serving testimony of Illumina's CEO—is misleading and incomplete because it makes vague suggestions about NGS competition broadly and how it could affect "profit pools" while citing no specifics about any company that would cause Illumina to have lower profits. Importantly, the proposed finding says nothing about Illumina's expected profits as it relates to the relevant market participants in this case—MCED testing customers—that only make up a very small percentage of Illumina's total revenue. In

fact, Mr. deSouza told investors that MCED customers account for "roughly 2% of [Illumina's] total revenue" and was aware of "maybe 20 out of [its] 6,600 customers who are targeting a commercial screening test." (CCFF ¶ 3140). The proposed finding's general claims about NGS competition—which are too vague to assess their validity or relevance to Illumina's ability and incentive to harm Grail's rivals—are of dubious evidentiary value.

The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. It disregards the fact that an upstream firm that faces no competition, such as Illumina, could nevertheless impose a substantial price increase on downstream rivals of Grail, or it could decide to engage in myriad other behaviors to disadvantage the downstream rivals, such as withholding or delaying access to new technology, reducing the quality of service, denying access to information and licenses necessary for FDA approval and commercialization, and sharing competitively sensitive information with Grail. (*See* CCFF ¶¶ 2702-3078). The proposed finding also adopts a myopic focus on price-related harms when harm to innovation is important for MCED testing competition. (*See* CCFF ¶¶ 3570-3668). In any event, the hypothetical posed by the proposed finding—and any suggestion that it illustrates the dynamics between Illumina and Grail's rivals—is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. (*See* CCFF ¶¶ 2607-3569). Therefore, this Court should disregard the proposed finding.

> 910.2 Mr. deSouza further noted, that NGS competition is "reflected in Illumina's pricing plans and strategy" in that it "shows up in our expectation of the price of sequencing in the market, and it's continuing to decline" and "in our expectations of sort of the margin evolution in the industry". (deSouza (Illumina) Tr. 2331–32.)

Response to Finding No. 910.2

The proposed finding is vague because it does not define "NGS competition," "reflected," "Illumina's pricing plans and strategy," "shows up," "expectation," "price of sequencing," "the market," "decline," "sort of the margin evolution, or "the industry."

The proposed finding—which relies on self-serving testimony of Illumina's CEO—is misleading and incomplete because it makes vague suggestions about NGS competition broadly and how it could affect "margins" while citing no specifics about any company that would cause Illumina to have lower margins. Importantly, the proposed finding says nothing about Illumina's expected profits as it relates to the relevant market participants in this case—MCED testing customers—that only make up a very small percentage of Illumina's total revenue. In fact, Mr. deSouza told investors that MCED customers account for "roughly 2% of [Illumina's] total revenue" and was aware of "maybe 20 out of [its] 6,600 customers who are targeting a commercial screening test." (CCFF ¶ 3140). The proposed finding's general claims about NGS competition—which are too vague to assess their validity or relevance to Illumina's ability and incentive to harm Grail's rivals—are of dubious evidentiary value.

The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. It disregards the fact that an upstream firm that faces no competition, such as Illumina, could nevertheless impose a substantial price increase on downstream rivals of Grail, or it could decide to engage in myriad other behaviors to disadvantage the downstream rivals, such as withholding or delaying access to new technology, reducing the quality of service, denying access to information and licenses necessary for FDA

approval and commercialization, and sharing competitively sensitive information with Grail. (*See* CCFF ¶¶ 2702-3078). The proposed finding also adopts a myopic focus on price-related harms when harm to innovation is important for MCED testing competition. (*See* CCFF ¶¶ 3570-3668). In any event, the hypothetical posed by the proposed finding—and any suggestion that it illustrates the dynamics between Illumina and Grail's rivals—is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. (*See* CCFF ¶¶ 2607-3569). Therefore, this Court should disregard the proposed finding.

> 910.3 Similarly, Dr. Febbo explained, "[w]e have dropped the cost of sequencing through our investment in R&D, through our kind of dogged focus on making sequencing more affordable, because in research what we saw is a term we called elasticity, where the less expensive the sequencing was, the more sequencing was performed, so that it made sense to continue to drop the cost." (Febbo (Illumina) Tr. 4329–30.)

Response to Finding No. 910.3

The proposed finding is misleading and incomplete to the extent it purports to suggest anything about NGS competition. In fact, Dr. Febbo is stating that lowering NGS costs expanded Illumina's profits: because "the less expensive the sequencing was, the more sequencing was performed," it "made sense to continue to drop the cost." He did not say that "it made sense to drop the cost" because Illumina faced a competitive threat for MCED testing. Indeed, the fact that Respondents decreased the price of sequencing and invested in R&D historically—despite experiencing very little competition for MCED testing—undercuts their claims that future estimates of lower NGS costs signify that Illumina will face NGS competition for MCED testing. A monopolist innovating to lower the cost of a product to expand its total profits does not indicate competition. *See* Richard J. Gilbert, *Competition and Innovation*, 1 J. Industrial Org. Ed. 8, 3-9 (2006) (illustrating how a monopolist with no competition will

nevertheless have an incentive to invest in innovation if it expects the profits from that innovation to exceed its current profits).

The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. The percentage of NGS costs as a portion of downstream MCED revenues or margins is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. It disregards the fact that an upstream firm that faces no competition, such as Illumina, could nevertheless impose a substantial price increase on downstream rivals of Grail, or it could decide to engage in myriad other behaviors to disadvantage the downstream rivals, such as withholding or delaying access to new technology, reducing the quality of service, denying access to information and licenses necessary for FDA approval and commercialization, and sharing competitively sensitive information with Grail. (*See* CCFF ¶¶ 2702-3078). The proposed finding also adopts a myopic focus on price-related harms when harm to innovation is important for MCED testing competition. (*See* CCFF ¶¶ 3570-3668). In any event, the hypothetical posed by the proposed finding—and any suggestion that it illustrates the dynamics between Illumina and Grail's rivals—is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. (*See* CCFF ¶¶ 2607-3569). Therefore, this Court should disregard the proposed finding.

911. Even if a large increase in input prices were permitted and Illumina had no reputational concerns, a downstream rival could completely absorb an increase of even, say, 100 percent, without materially affecting their margins. (RX3864 (Carlton Expert Report) ¶ 75, n.208.)

Response to Finding No. 911

The proposed finding is vague because it does not define "large increase," "input prices," "permitted," "reputational concerns," "completely absorb," "an increase," "materially affecting"

or "margins."

The proposed finding is unsupported because it relies on Respondents' own expert report for a factual proposition. No factual evidence is cited. Moreover, this Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite the self-serving report of their own economic expert, Dr. Carlton, as the only source of evidence supporting this fact in contravention of this Court's order. The Court should disregard this evidence.

The proposed finding is unsupported and misleading. [redacted] even though Illumina, as the dominant provider of NGS products and services, could likely extract even greater price increases through a raising rivals' costs strategy due to the absence of NGS competitors. (*See generally* CCFF ¶¶ 1019-1200).

The proposed finding is misleading and incomplete to the extent it suggests anything about Illumina's ability and incentive to harm Grail's rivals. [redacted] is irrelevant for whether Illumina will have the ability and incentive to harm Grail's rivals. It disregards the fact that an upstream firm that faces no competition, such as Illumina, could nevertheless impose a substantial price increase on downstream rivals of Grail, or it could decide to engage in myriad other behaviors to

disadvantage the downstream rivals, such as withholding or delaying access to new technology, reducing the quality of service, denying access to information and licenses necessary for FDA approval and commercialization, and sharing competitively sensitive information with Grail. (*See* CCFF ¶¶ 2702-3078). The proposed finding also adopts a myopic focus on price-related harms when harm to innovation is important for MCED testing competition. (*See* CCFF ¶¶ 3570-3668). In any event, the hypothetical posed by the proposed finding—and any suggestion that it illustrates the dynamics between Illumina and Grail's rivals—is contradicted by the weight of the evidence that clearly shows Illumina will have the ability and incentive to foreclose or otherwise disadvantage Grail's rivals. (*See* CCFF ¶¶ 2607-3569). Therefore, this Court should disregard the proposed finding for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

> 911.1 For example, even in the absence of the contractual prohibition on raising costs, if Illumina doubled the prices it charges for its instruments, consumables, and services, and the GRAIL rival left its test price unchanged, the rival would see only a nominal decline in profits. (RX3864 (Carlton Expert Report) ¶ 75, n.208.)

Response to Finding No. 911.1

[redacted]

[redacted]

911.2 [redacted]

Response to Finding No. 911.2

[redacted]

[redacted]

911.3 It is inconceivable that even this very large increase in Illumina's input price would have a large effect on the competitiveness of downstream firms. (RX3864 (Carlton Expert Report) ¶ 75, n.208.)

Response to Finding No. 911.3

[redacted]

[redacted]

912. [redacted]

Response to Finding No. 912

[redacted]

[redacted]

[redacted]

[redacted]

4. [redacted]

913. [redacted]

Response to Finding No. 913

[redacted]

[redacted]

914. [redacted]

Response to Finding No. 914

[redacted]

[redacted]

915. Dr. Scott Morton fails to address whether she believes the large price increases that would be required to raise rivals' costs meaningfully are likely or indicate the magnitude of such increases or assess the negative impacts that such increases could have on Illumina's business. (RX3864 (Carlton Expert Report) ¶ 65.)

Response to Finding No. 915

[redacted]

[redacted]

H. Complaint Counsel's Theory Ignores Intensifying Upstream Competition.

1. Relevance Of Current And Future Upstream Competition.

916. A necessary condition for a vertical merger to harm competition in the relevant market is a limited ability by the merged firm's rivals to switch their purchases of the related product to sufficiently close substitutes. (RX3871 (Willig Expert Report) ¶ 41, n.59; RX3701 (Vertical Merger Guidelines) at 4-5).)

Response to Finding No. 916

The proposed finding is misleading to the extent it implies that Complaint Counsel needs to define a related product market or otherwise show upstream monopoly. As explained by Complaint Counsel's post-trial briefing, Complaint Counsel is not required to define a market or prove that Illumina is a monopolist. (Complaint Counsel's Post-Trial Brief at 66-71).

Complaint Counsel also objects to this proposed finding as improper expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* RX3871 (Willig Expert Report); PX7132, (Willig Dep.)). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness,

2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . .shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as improper expert opinion. Therefore, this Court should disregard the proposed finding.

> 916.1 Complaint Counsel was required to establish that Illumina has a monopoly over platforms viable for MCED development, and that there will be no viable substitutes (from the standpoint of MCED test developers that could potentially compete with Galleri) for Illumina's NGS platforms during the relevant time period. (RX3871 (Willig Expert Report) ¶ 41.)

Response to Finding No. 916.1

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). The proposed finding is misleading to the extent it implies that Complaint Counsel needs to define a related product market or otherwise show upstream monopoly. As explained by Complaint Counsel's post-trial briefing, Complaint Counsel is not required to define a market or prove that Illumina is a monopolist. (Complaint Counsel's Post-Trial Brief at 66-71).

Complaint Counsel also objects to this proposed finding as improper expert testimony

offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))).

[redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . .shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as improper expert opinion.

917. The presence of current and future NGS competitors is significant "in two ways. First, if you could substitute to another company, then that constrains what Illumina can do. . . [Second], [e]ven if you can't switch immediately, the fact that these technologies might be available . . . in the future, you really want to be focusing on not what is possible today, but you . . . really want to be talking about what are the alternatives in the future when the MCED market, to . . . when the MCED industry develops more fully." (RX6000 (Carlton Trial Dep. at 36).)

Response to Finding No. 917

The proposed finding is misleading and contrary to the weight of substantial evidence to the extent Respondents suggest that MCED test developers can switch to another NGS platform currently or will likely be able to in the foreseeable future. First, [redacted] (CCFF ¶¶ 1229-68, 1286-95, 1302-19, 1325-45, 1370-98). Second, [redacted] (CCFF ¶¶ 1286-95, 1302-19, 1325-45, 1370-98, 1613-20, 1646-48, 1677-83, 1717-23). Moreover, there are no NGS platforms in development that are likely to replace Illumina. (CCFF ¶¶ 1724-31).

The proposed finding is also incorrect and contrary to the weight of substantial evidence to the extent it suggests that MCED test developers can readily switch to other NGS platforms. MCED tests are developed to run on a specific NGS platform and switching to another theoretical platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (CCFF ¶¶ 1768-1901).

The proposed finding is also vague and ambiguous in Dr. Carlton's phrasing of [redacted] The MCED test developers are in the process of innovating and developing competing tests to Grail's Galleri test and theoretical NGS platforms that may be developed when the "industry develops more fully" is ambiguous. At this time, competitors are racing to develop MCED tests and are using Illumina's NGS platform exclusively. (CCFF Section VI.).

Furthermore, no NGS platform is likely to enter the NGS market that would be a viable option for MCED test developers in a timely manner. (CCFF ¶¶ 1576-1731). The Proposed Finding should be disregard for the reasons stated herein and in Responses to RPFF ¶¶ 1934-1946.

918. The presence of upstream NGS alternatives on the market and in development, and the constraints they impose on Illumina, must be taken into account in any economic analysis of Illumina's post-merger incentives and ability to substantially foreclose MCED competition. (*Supra* at [●].)

Response to Finding No. 918

[redacted]

[redacted]

2. **The Evidence Shows Current And Future Upstream Competition.**

919. There are today alternatives to Illumina as a provider of NGS sequencing products and services. (*Supra* PFF ¶¶ 777–779.)

Response to Finding No. 919

The proposed finding is misleading and contrary to the weight of substantial evidence to the extent Respondents suggest that MCED test developers have an alternative NGS platform that they can switch to at this time or in the foreseeable future. The proposed finding is also misleading as it conflates the availability of general NGS alternatives to NGS alternatives that meet the needs of MCED test developers. First, [redacted]. (CCFF ¶¶ 1229-68, 1286-95, 1302-19, 1325-45, 1370-98). [redacted]. (CCFF ¶¶ 1286-95, 1302-19, 1325-45, 1370-98, 1613-20, 1646-48, 1677-83, 1717-23). Furthermore, no NGS platform is likely to enter the NGS market that would be a viable option for MCED test

developers in a timely manner. (CCFF ¶¶ 1576-1731). And there are no NGS platforms in development that are likely to replace Illumina. (CCFF ¶¶ 1724-31). Even if a company develops a new NGS platform, significant barriers to commercialization exist and it will take years for a new entrant to gain the reputation and enough widespread commercial use to be an option to MCED test developers. (CCFF ¶¶ 1527-1575). Therefore, this Court should disregard the proposed finding.

919.1 Suppliers such as Thermo Fisher ONT and Singular are available on the market today and can be used for MCED test development. (*Supra* PFF ¶¶ 778–779.)

Response to Finding No. 919.1

The proposed finding is incomplete, misleading, and against the weight of substantial evidence to the extent Respondents suggest that Thermo Fisher, Oxford Nanopore (ONT), and Singular can be used for MCED test development today. [redacted]

(CCFF ¶¶ 1229-68, 1286-95, 1302-19, 1325-45, 1370-98).

[redacted]

[redacted]

This proposed finding is also incomplete, misleading, and against the weight of substantial evidence to the extent it implies Oxford Nanopore's NGS platform would be a viable alternative for MCED test developers. Oxford Nanopore, and any other long-read NGS platform, is not an option for MCED test developers. [redacted]. (CCFF ¶¶ 1346-1369). [redacted] Further, Dr. Bert Vogelstein of Johns Hopkins University testified that "[l]ong-read sequencers are [ ] unsuited for early detection [cfDNA] liquid biopsy testing" in part because "the throughput of long-read sequencers are much lower than the throughput of short-read sequencers" and "the error rates of long-read sequencers are much too high to effectively analyze the molecules and plasma". (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

This proposed finding is also incomplete, misleading, and against the weight of

substantial evidence to the extent it implies Singular's NGS product in development would be a viable alternative for MCED test developers. [redacted] Singular also represented to its investors that it expects to be sued by Illumina after it launches its G4 platform, which could prevent Singular from commercializing its NGS platform, (CCFF ¶¶ 1668-76), concerns that are echoed by MCED test developers. [redacted]. Singular has also not generated any revenue and expects to incur significant losses in the near term (PX0068 at 35 (Singular Genomics S-1, May 2021)). [redacted] (CCFF ¶¶ 1679-83; *see also* CCFF ¶¶ 1537-55 (describing that MCED customers would not switch to a new NGS platform until it has widespread adoption and demonstrated reliability); CCFF ¶¶ 1556-1566 (gaining widespread

adoption among customers is time consuming and difficult)). Therefore, this Court should disregard the proposed finding.

920. A number of other companies are poised to offer NGS sequencing products and services in the near term. (*Supra* PFF ¶¶ 782–787.)

Response to Finding No. 920

The proposed finding is incomplete, misleading, and against the weight of substantial evidence to the extent Respondents suggest that there are other companies that will offer NGS sequencing products "in the near term" that can be used for MCED test development. [redacted] (CCFF ¶¶ 1229-68, 1286-95, 1302-19, 1325-45, 1370-98). [redacted] CCFF ¶¶ 1286-95, 1302-19, 1325-45, 1370-98, 1613-20, 1646-48, 1677-83, 1717-23).

This proposed finding is also incomplete, misleading, and against the weight of substantial evidence to the extent it implies Singular's NGS product in development would be a viable alternative for MCED test developers. [redacted]

[redacted] Singular also represented to its investors that it expects to be sued by Illumina after it launches its G4 platform, which could prevent Singular from commercializing its NGS platform, (CCFF ¶¶ 1668-76), concerns that are echoed by MCED test developers. [redacted]. Singular has also not generated any revenue and expects to incur significant losses in the near term (PX0068 at 23 (Singular Genomics S-1, May 2021)). In fact, Singular identified as a risk to investors that "we may require substantial additional funding" and substantial additional funding is not available Singular may be required to "delay, scale back, or cease our product development or commercialization activities." (PX0068 at 35 (Singular Genomics S-1, May 2021)). [redacted] (CCFF ¶¶ 1679-83; *see also* CCFF ¶¶ 1537-55 (describing that MCED customers would not switch to a new NGS platform until it has widespread adoption and demonstrated reliability); CCFF ¶¶ 1556-1566 (gaining widespread adoption among customers is time consuming and difficult)).

[redacted]

[redacted]

[redacted]

Furthermore, no NGS platform is likely to enter the NGS market that would be a viable option for MCED test developers in a timely manner. (CCFF ¶¶ 1576-1731). And there are no NGS platforms in development that are likely to replace Illumina. (CCFF ¶¶ 1724-31). Even if a company develops and launches a new NGS platform, significant barriers to commercialization exist and it will take years for a new entrant to gain the reputation and enough widespread commercial use to be considered as an option to MCED test developers. (CCFF ¶¶ 1527-1575). Therefore, this Court should disregard the proposed finding.

921. There is substantial evidence that MCED test developers will have many commercially viable NGS options within the next few years, before most, if not all, MCED tests in development are ready for commercial launch. (*Supra* PFF ¶¶ 782–787.)

Response to Finding No. 921

The proposed finding is egregiously misleading, ambiguous, and against the weight of substantial evidence demonstrating that MCED test developers will not have any commercially viable NGS options within the next few years. The proposed finding is misleading to the extent that is suggests that MCED tests do not rely on NGS sequencers prior to commercialization. The proposed finding is ambiguous because "commercially viable NGS options" is not defined and the fact that a new NGS platform may launch does not mean it is applicable for MCED test developers. (CCFF ¶¶ 1576-1731). Substantial evidence demonstrates that no NGS platform is likely to enter the NGS market that would be a viable option for MCED test developers in a timely manner. (CCFF ¶¶ 1576-1731). And there are no NGS platforms in development that are

likely to replace Illumina. (CCFF ¶¶ 1724-31).

The proposed finding is also highly misleading because it implies that MCED test developers can easily switch to a new NGS platform if, and/or when, one launches. Switching to another hypothetical NGS platform would cause significant delays, require significant costs, and pose serious regulatory and financial risks for MCED test developers. (CCFF ¶¶ 1768-1901).

[redacted] Moreover, even if a company develops and launches a new NGS platform, significant barriers to commercialization exist and it will take years for a new entrant to gain the reputation and enough widespread commercial use to be considered as an option to MCED test developers. (CCFF ¶¶ 1527-1575); *see also* Response to RPFF ¶ 920. Therefore, this Court should disregard the proposed finding.

922. For example, BGI will enter the U.S. market not long after Illumina's patents that underlie the injunction against BGI's entry expire in 2023, and it is undisputed that BGI's technology is comparable to Illumina's NGS systems in terms of throughput, accuracy, turnaround time and cost. (*Supra* PFF ¶¶ 777.)

Response to Finding No. 922

[redacted]

[redacted]

923. There are hundreds of millions of dollars being invested to fund these NGS innovators, many of which are specifically targeting the screening (and other oncology) segments and have disclosed roadmaps that project commercial launch within the next few years—and in the case of Singular, late last year. (*Supra* PFF ¶¶ 782–787; Velarde (Singular) Tr. 4515–16 ("we're going to be commercially launching at the end of [2021] and shipping systems in the first half of next year").)

Response to Finding No. 923

The proposed finding is incomplete, highly misleading, and against the weight of substantial evidence to the extent Respondents suggest that the investment into NGS innovators will result in an alternative NGS platform for MCED test developers that would be timely, likely, and sufficient. Substantial evidence demonstrates that no NGS platform is likely to enter the NGS market that would be a viable option for MCED test developers in a timely manner. (CCFF ¶¶ 1576-1731). And there are no NGS platforms in development that are likely to replace Illumina. (CCFF ¶¶ 1724-31).

The proposed finding is also highly misleading because it implies that MCED test

developers can easily switch to a new NGS platform if, and/or when, one launches. Switching to another hypothetical NGS platform would cause significant delays, require significant costs, and pose serious regulatory and financial risks for MCED test developers. (CCFF ¶¶ 1768-1901).

[redacted] Moreover, even if a company develops and launches a new NGS platform, significant barriers to commercialization exist and it will take years for a new entrant to gain the reputation and enough widespread commercial use to be considered as an option to MCED test developers. (CCFF ¶¶ 1527-1575); *see also* Response to RPFF ¶ 920. Therefore, this Court should disregard the proposed finding.

> 923.1 A number of these innovators are led by former Illumina executives, who are extremely knowledgeable about the industry and what it takes to succeed. Moreover, in speculating that all of these well-funded, serious players will simply fail, Complaint Counsel adopts an entirely inconsistent position on the evidence. (*Supra* PFF ¶¶ 782–787, 789.)

Response to Finding No. 923.1

[redacted]

[redacted]

924. Numerous Illumina executives testified about their expectations for NGS competition, including with the expiration of key patents in 2023, and how that dynamic impacts Illumina's strategies. (PFF ¶¶ 924.1–924.3.)

Response to Finding No. 924

The proposed finding is misleading, unreliable, and inherently speculative. For support, Respondents cite only to unfounded, self-serving testimony of Illumina executives that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executives' conjectures, this proposed finding of fact should be disregarded. The weight of substantial evidence is clear that there are no likely entrants that can serve as an alternative to MCED test developers, and even if there was a potential entrant, the switching costs and significant barriers to commercialization are enormous. *See, e.g.*, Responses to RPFF ¶¶ 919-923. Specifically, Respondents ordinary course documents show that Illumina is already seeking *additional injunctive relief* against BGI based on U.S. patents that do not expire until 2027 and may assert additional patents against BGI that run beyond 2027. (CCFF ¶¶ 1276-1285). Therefore, this Court should disregard the proposed finding.

924.1 [redacted]

Response to Finding No. 924.1

[redacted]

924.2 Ms. Berry testified that "there are numerous competitors already participating in the genomics space with instruments and consumables similar to ours", and "we anticipate that that competitive environment will . . . only become more intensive over time." (Berry (Illumina) Tr. 813).

Response to Finding No. 924.2

The proposed finding is misleading, inherently speculative, and against the weight of the evidence. For support, Respondents cite to Mr. Berry's unfounded, self-serving testimony as an Illumina executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for this executive's conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that there are alternative NGS platforms comparable to Illumina "already participating in the genomics space" or that the "competitive environment" for such platforms will "become more intensive over time" for MCED test developers. First, the mere potential of a new NGS platform does not at all suggest that these potential entrants will serve as a viable alternative specifically to MCED test developers. The voluminous record evidence demonstrates that no NGS platform is likely to enter the NGS market that would be a viable option for MCED test developers in a timely manner. (CCFF ¶¶ 1576-1731). [redacted] Moreover, even if a company develops and launches a new NGS platform, significant barriers to commercialization exist and it will take years for a new entrant to gain the reputation and enough widespread commercial use to be considered as an option to MCED test developers. (CCFF ¶¶ 1527-1575); *see also* Response to

RPFF ¶ 920. Therefore, this Court should disregard the proposed finding.

> 924.3 Dr. Aravanis similarly testified that there will be "many new sequencing platforms, so a tremendous intensification of competition" and "there will be even more platforms in the coming years." (Aravanis (Illumina) Tr. 1866).

Response to Finding No. 924.3

The proposed finding is misleading, inherently speculative, and against the substantial weight of the evidence. For support, Respondents cite to Dr. Aravanis's unfounded, self-serving testimony as an Illumina executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for this executive's conjecture, this proposed finding of fact should be disregarded. In addition, the proposed finding is misleading because the testimony is not specific to NGS platforms that can be used as an alternative to Illumina's NGS platform for MCED test developers.

The proposed finding is misleading and against the substantial weight of the evidence to the extent Respondents suggest that there will be "many new sequencing platforms" comparable to Illumina's NGS platforms or that such platforms will be applicable for MCED test developers. First, the mere potential of a new NGS platform does not at all suggest that these potential entrants will serve as a viable alternative specifically to MCED test developers. The voluminous record evidence demonstrates that no NGS platform is likely to enter the NGS market that would be a viable option for MCED test developers in a timely manner. (CCFF ¶¶ 1576-1731). And there are no NGS platforms in development that are likely to replace Illumina. (CCFF ¶¶ 1724-31). [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

924.4 Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.)

Response to Finding No. 924.4

The proposed finding is incomplete, misleading, inherently speculative, and against the weight of substantial evidence. For support, Respondents cite to Dr. Aravanis's unfounded, self-serving testimony as an Illumina executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for this executive's conjecture, this proposed finding of fact should be disregarded.

The proposed finding is incomplete, misleading, and against the weight of substantial evidence to the extent Respondents suggest that the [redacted]

[redacted]

925. Furthermore, it is well accepted that sequencing technology is becoming substantially cheaper every year – it is thus substantially likely that all existing and future sequencing options will improve and become cheaper over time. (PFF ¶ 22.)

Response to Finding No. 925

[redacted]

[redacted]

926. Complaint Counsel infers from the mere fact of "excitement" and "investment" in downstream test development that it is "highly likely that there are going to be several successful cancer tests" in the alleged MCED market. (RX3852 (Scott Morton Dep. at 112).) There is no basis to accept that MCED test developers will be successful and compete with Galleri, yet the upstream alternatives to Illumina in development are too uncertain to predict their likely success. (RX6000 (Carlton Trial Dep. at 37–38).)

Response to Finding No. 926

The proposed finding is incomplete, egregiously misleading, and against the weight of substantial evidence to the extent Respondents suggest that Grail's competitors are not racing to develop MCED tests, are not likely to compete with Grail, and that there are likely upstream alternatives to Illumina that will be available for MCED test developers. In addition, this proposed finding is inherently speculative. For support, Respondents cite only to the paid testimony of Dr. Carlton's that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the expert's conjecture, this proposed finding of fact should be disregarded under this Court's prior order.

Complaint Counsel does not infer that it is "highly likely that there are going to be several successful cancer tests" in the MCED test market solely on the basis of "excitement" and "investment" in MCED tests. [redacted]

Instead, the record shows that MCED test developers are not merely beginning the race towards commercialization of an MCED test but are well on their way towards the finish line. Specifically, MCED test developers have already invested millions of dollars and years of

research into their MCED tests. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

926.1 As Dr. Carlton put it:

> "[A]ll I can do is point out the asymmetry in [the government's expert's] analysis. None of the MCED products that [Dr. Scott Morton is] talking about exist. . . . All of them are in the future and some, as I read the evidence, far in the future. In contrast, when she's evaluating NGS alternatives to Illumina, even though those seem from the evidence to be more readily available and likely, she dismisses them. So I agree it's hard to make predictions, very hard, as to who will be an actual competitor in the future. That's true both for MCED and NGS, and she takes a very asymmetric stance in which she assumes that the MCED products are going to come into existence, but the NGS alternatives to Illumina are not."

(RX6000 (Carlton Trial Dep. at 37–38).)

Response to Finding No. 926.1

This proposed finding is inherently speculative and egregiously incomplete, misleading, and against the weight of substantial evidence. For support, Respondents cite only to the paid testimony of Dr. Carlton that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for his unsupported conjecture, this proposed finding of fact should be disregarded.

[redacted]

[redacted]

Instead, the record shows that MCED test developers are not merely beginning the race towards commercialization of an MCED test but are well on their way towards the finish line. Specifically, MCED test developers have already invested millions of dollars and years of research into their MCED tests. [redacted]. And, despite Respondents' misrepresentations to the contrary, several of these MCED test developers are poised to cross the finish line and launch an MCED test imminently. [redacted]

[redacted]

3. The FTC's Theory Is Belied by Investment Activity Before and Since the Announcement of the GRAIL Merger Agreement

927. Numerous companies have been investing in the liquid biopsy early cancer detection space, since both before and after Illumina announced its agreement to acquire GRAIL. (RX3871 (Willig Expert Report) ¶¶ 50–51.)

Response to Finding No. 927

The proposed finding should be disregarded as violating this Court's order. This Court ordered that experts shall not be cited to "support factual propositions that should be established

by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Willig as the only source of evidence supporting the fact in contravention of this Court's Order. This Court should disregard this evidence.

Complaint Counsel objects to this proposed finding as improper expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as improper expert opinion.

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted]

Finally, the proposed finding is against the weight of the evidence. [redacted] Therefore, this Court should disregard the proposed finding.

928. Shortly after the merger was announced, analysts predicted that the deal would accelerate investment and innovation in the space, with one observing that "the recent acquisition of GRAIL by ILMN has catalyzed the excitement in the market to new highs – even ahead of our prior expectations", and "there is an expectation that more companies will increasingly pursue liquid biopsy screening as ILMN's acquisition of pre-revenue GRAIL has 'validated' the liquid biopsy early detection theses." (RX1096 (SVBLeerink) at 3.)

Response to Finding No. 928

The proposed finding is incomplete, vague, speculative, and misleading. The proposed finding is vague because "investment and innovation in the space" does not define which space it is referring to and does not necessarily refer to MCED test development. The proposed finding is incomplete and speculative, and thus should be disregarded, because Respondents cite to a *single* analyst report for the proposition that Illumina's acquisition of Grail will result in more companies pursuing liquid biopsy screening and/or MCED tests.

The proposed finding is also misleading to the extent Respondents suggest that

investment in other MCED test developers post-announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise those rivals' costs post-transaction. [redacted]

[redacted]

The proposed finding also should be disregarded as it is based on unreliable hearsay. Respondents cite only an out-of-court statement of investors for this fact but choose to not to call any of the investors at trial to provide context or an indicia of reliability. Therefore, this Court should disregard the proposed finding.

929. Investment has in fact poured into cancer test development since the time Illumina announced its agreement to acquired GRAIL. (RX3871 (Willig Expert Report) ¶ 50.)

Response to Finding No. 929

The proposed finding is vague, misleading, irrelevant, unsupported, and against the weight of the evidence. The finding is vague given that it is unclear what is meant by "cancer test development". Moreover, the finding is irrelevant: [redacted]

Complaint Counsel objects to this proposed finding as improper expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a

new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as improper expert opinion.

Finally, as Complaint Counsel explained, the overwhelming weight of the evidence shows that [redacted]. Therefore, this Court should disregard the proposed finding.

> 929.1 For example, approximately one month after Illumina announced its agreement to acquire GRAIL, Exact entered into an agreement acquire Thrive for over $2 billion, and completed the acquisition approximately four months after Illumina announced its agreement to acquire GRAIL. (RX3196 (Exact) at 1.)

Response to Finding No. 929.1

The proposed finding is misleading to the extent Respondents suggest that Exact's acquisition of Thrive after the announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise

those rivals' costs post-transaction. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

929.2 [redacted]

Response to Finding No. 929.2

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

929.3 As another example, in December 2020, Singlera obtained $150 million in financing, which it planned to utilize "mainly to expand the company's early cancer screening product research and development pipeline and focus on promoting product registration and commercialization, as well as expanding prospective studies into pan-cancer early screening." (RX3633 (PR Newswire) at 1); [redacted]

Response to Finding No. 929.3

The proposed finding is based only on out-of-court hearsay that has no indicia of reliability as well as an impermissible factual citation to an expert report. This proposed finding should be disregarded based on that alone. The proposed finding is misleading to the extent Respondents suggest that Singlera's $150 million in additional financing after the announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise those rivals' costs post-transaction. [redacted]

[redacted]

[redacted]

930. As Mr. deSouza observed, in addition to Thrive's acquisition of Exact, other liquid biopsy companies experienced large rounds of investments after Illumina announced its agreement to acquire GRAIL, including a significant increase in investment in the early cancer detection space. (deSouza (Illumina) Tr. 2392–93.)

Response to Finding No. 930

The proposed finding is misleading to the extent Respondents suggest that a "significant increase in investment in the early cancer detect space" after the announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise those rivals' costs post-transaction. [redacted]

[redacted]

[redacted]

930.1 This "was very consistent with what we saw in the noninvasive prenatal testing space [another downstream testing space, discussed below, that Illumina entered through a vertical merger and that is now thriving competitively] when we entered in 2013 – investment increased there too." (deSouza (Illumina) Tr. 2392–93.)

Response to Finding No. 930.1

The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza, to assert that Illumina's acquisition of Verinata resulted in increased investment in the NIPT market. This proposed finding should be disregarded as Respondents only cite to self-serving testimony of Mr. deSouza that is uncorroborated by any ordinary course documents or analysis.

[redacted]

[redacted]

931. Firms raised capital at least partly directed towards the development of NGS-based cancer screening tests after Illumina announced in September 2020 that it would be acquiring GRAIL, signaling an expectation that Illumina's alleged ability and incentive to increase prices or diminish its service to firms that are developing NGS-based cancer screening tests will be constrained. (RX3871 (Willig Expert Report) ¶ 51, n.104) (citing (RX3015 (GlobeNewswire) at 1); (RX3075 (BusinessWire) at 1); (RX3170 (PR Newswire) at 1).)

Response to Finding No. 931

The proposed finding is misleading, irrelevant, unsupported, and against the weight of the

evidence. [redacted]

Complaint Counsel objects to this proposed finding as improper expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as

improper expert opinion.

Respondents provide two other sources to support their contention, RX3170 and RX3075. Respondents did not depose or call either investment firm to testify at trial and to explain why each firm invested in early cancer detection companies. Without that context, these articles are not probative as to each investment firms' motivations for investing, understanding of the MCED industry, or expectations regarding this enforcement action. As such, the proposed finding should be disregarded as unsupported by any cited source.

The proposed finding is misleading to the extent Respondents suggest that investment in companies developing MCEDs after the announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise those rivals' costs post-transaction. [redacted]

[redacted]

Finally, as Complaint Counsel explained, the overwhelming weight of the evidence shows that [redacted]

932. The timing and amount of investment activity in cancer test development is directly contrary to Complaint Counsel's speculation that the merger will disincentivize investment in NGS cancer screening.

Response to Finding No. 932

First, the proposed finding should be disregarded because it is entirely unsupported and lacks any citation to the record. Second, the proposed finding is incomplete and misleading to the extent [redacted] Therefore, the proposed finding should be disregarded.

933. The timing and amount of investment activity in cancer test development is directly contrary is also inconsistent with Complaint Counsel's claim that test developers are "captive" to Illumina and locked in to Illumina platforms with no options even if Illumina disadvantaged their tests. According to Complaint Counsel, customers are and will remain locked into Illumina's NGS platform, they would have no choice but to pay the higher price demanded by Illumina. This concept is commonly referred to by economists as the "hold-up problem." (RX3871 (Willig Expert Report) ¶ 52.)

Response to Finding No. 933

The proposed finding is misleading, irrelevant, unsupported, and against the weight of the evidence. The finding is irrelevant: [redacted]

Moreover, the proposed finding is misleading to the extent Respondents suggest that investment after the announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise those rivals' costs post-transaction. [redacted]

[redacted]

The proposed finding is also unsupported given the only source is Dr. Willig's improper expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to

Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as improper expert opinion. Given that Respondents have not provided the support of their substituted expert – Dr. Katz – or any other fact witnesses, this testimony is unsupported and should be disregarded.

Finally, as Complaint Counsel explained, the overwhelming weight of the evidence shows that [redacted]. Therefore, this Court should disregard the proposed finding.

934. However, the substantial investment in liquid biopsy cancer test development on Illumina's platform, by itself, refutes the notion that MCED test developers are indefinitely locked into Illumina's platform or that they fear Illumina can impede their test development efforts. (RX6004 (Katz Trial Dep. at 43–44).)

Response to Finding No. 934

First, this Court held that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here, Respondents cite Dr. Katz in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. As such, this Court should disregard this proposed finding.

Second, Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forty to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4) ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

The proposed finding should also be disregarded because Dr. Katz himself did not conduct any actual assessment of investments in the liquid biopsy or MCED development

industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Further, Dr. Katz did not communicate with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)).

[redacted]

935. That is because it would be economically irrational for firms to make such large investments if they truly anticipated that they would have no options or opportunities to switch by the time their tests are commercialized and earning profits. (RX6004 (Katz Trial Dep. at 43–44).)

Response to Finding No. 935

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forty to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness

report.”); [redacted]

[redacted] Given the unreliable nature of Dr. Katz’s opinion as well as Respondents’ complete disregard of this Court’s order, Dr. Katz’s opinion should be disregarded.

The proposed finding should also be disregarded because Dr. Katz himself did not conduct any actual assessment of investments in the liquid biopsy or MCED development industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Further, Dr. Katz did not communicate with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)).

[redacted]

[redacted]

936. Otherwise, these firms would be knowingly subjecting themselves to opportunistic hold-up, since (if Complaint Counsel's long-term monopoly theory had merit) Illumina would have both an incentive and ability to extract all their returns, even *without* the GRAIL merger. (RX6004 (Katz Trial Dep. at 43–44); RX3871 (Willig Expert Report) ¶¶ 52–54.)

Response to Finding No. 936

The proposed finding is misleading, against the weight of the evidence, and should be disregarded based on the unsupported, speculative testimony from Dr. Katz and Dr. Willig. [redacted] The proposed finding is misleading to the extent Respondents suggest that a investment after the announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise those rivals' costs post-transaction. [redacted]

[redacted]

936.1 [redacted]

Response to Finding No. 936.1

[redacted]

The proposed finding is misleading to the extent Respondents suggest that investment after the announcement of the Illumina/Grail transaction is indicative that Illumina would not have the ability and incentive to foreclose Grail's rivals or otherwise raise those rivals' costs post-transaction. [redacted]

[redacted]

The proposed finding is also irrelevant: [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

936.1.1 [redacted]

[redacted]

Response to Finding No. 936.1.1

[redacted]

[redacted]

[redacted]

[redacted]

.

[redacted]

[redacted]

[redacted]

[redacted]

936.2 [redacted]

Response to Finding No. 936.2

[redacted]

936.3 [redacted]

[redacted]

Response to Finding No. 936.3

[redacted]

[redacted]

936.4 [redacted]

[redacted]

Response to Finding No. 936.4

[redacted]

[redacted]

937. The investment activity by these Illumina customers are a compelling market signal—one backed by large sums of money, not just words—that NGS-based test developers expect that competition will powerfully constrain Illumina's ability and incentive to increase prices or diminish its service to firms that are developing NGS-based cancer screening tests. (RX3871 (Willig Expert Report) ¶ 57.)

Response to Finding No. 937

The proposed finding is misleading, irrelevant, unsupported, and against the weight of the

evidence. The finding is irrelevant: [redacted]

The proposed finding is also unsupported given the only source is Dr. Willig's improper expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as

improper expert opinion. Given that Respondents have not provided the support of their substituted expert – Dr. Katz – or any other fact witnesses, this testimony is unsupported and should be disregarded.

The proposed finding is misleading to the extent it implies that post-acquisition investment indicates that Illumina does not have the ability or incentive to foreclose Grail's rivals. [redacted]

[redacted]

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted]

Finally, as Complaint Counsel explained, the overwhelming weight of the evidence shows that [redacted]. Therefore, this Court should disregard the proposed finding.

938. Even after Illumina announced in September 2020 that it would be acquiring GRAIL, the marketplace continued to show strong signals that Illumina's alleged ability and incentive to increase prices or diminish its service to firms that are developing NGS-based cancer screening tests will be constrained, as evidenced by the investment activity occurring after the announcement. (RX3871 (Willig Expert Report) ¶ 58.)

Response to Finding No. 938

The proposed finding is misleading, irrelevant, unsupported, and against the weight of the evidence. The finding is irrelevant: [redacted]

The proposed finding is also unsupported given the only source is Dr. Willig's improper

expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as improper expert opinion. Given that Respondents have not provided the support of their substituted expert – Dr. Katz – or any other fact witnesses, this testimony is unsupported and should be disregarded.

The proposed finding is also misleading to the extent that Respondents are implying that post-Acquisition Respondents will not have the ability and incentive to disadvantage Grail's

rivals. [redacted]

Finally, as Complaint Counsel explained, the overwhelming weight of the evidence shows that [redacted]. Therefore, this Court should disregard the

proposed finding.

938.1 [redacted]

Response to Finding No. 938.1

[redacted]

[redacted]

938.2 In other words, even without the merger, economic logic states that, if (contrary to fact) Illumina were a long-term monopolist of NGS platforms for MCED development, it would extract all the profits by raising prices of NGS inputs once the downstream developers have "invented the relevant technology." (RX6004 (Katz Trial Dep. at 43–44); RX3852 (Scott Morton Dep. at 171).)

Response to Finding No. 938.2

The proposed finding is irrelevant, unsupported by the factual record, misleading, and contrary to the weight of the evidence. [redacted]

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted]

[redacted]

Finally, as Complaint Counsel explained, the overwhelming weight of the evidence shows that [redacted]. Therefore, this Court should disregard the proposed finding.

939. The substantial investment in NGS-based tests indicates that Complaint Counsel's long-term monopoly theory is unfounded. (RX6004 (Katz Trial Dep. at 43–44); (RX3871 (Willig Expert Report) ¶ 50.))

Response to Finding No. 939

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other

information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

The proposed finding should also be disregarded because neither Dr. Willig nor Dr. Katz conducted any actual assessment of investments in the liquid biopsy or MCED development industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Likewise, Dr. Willig did not assess whether investment would have been higher or lower but for the Illumina/Grail transaction and Dr. Willig did not speak to any investors in conducting his analysis. (PX7132 (Willig Dep. at 268, 270)). Dr. Katz also did not communicate with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)). Further, Dr. Willig agreed that government enforcement actions can impact investment decisions. (PX7132 (Willig Dep. at 271)).

[redacted]

[redacted]

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

940. Dr. Scott Morton has attempted to explain away this economic evidence by claiming that, absent the merger, the market would develop into a "bilateral monopoly" where there would be only one or a few winning MCED test developers, who would then have sufficient bargaining leverage to "divid[e] the rent" with Illumina, but this claim is without support. (RX3852 (Scott Morton Dep. at 172 ("So while Illumina would like to expand the market and have more sales and the tests can't [be] delivered without Illumina's product, likewise, tests can't be delivered without the MCED developers' product. So it's a case of a bilateral monopoly. If you think just the MCED developer and Illumina, and that means that they will be dividing the rent. . . . [The] [p]rospect of those rents is what is inducing investment in entry is what I'm trying to say.").)

Response to Finding No. 940

The proposed finding is incomplete and misleading. Respondents mischaracterize Dr. Scott Morton's testimony by adding their own interpretation of the term "bilateral monopoly." Dr. Scott Morton never described "bilateral monopoly" as a market in which "there would be only one or a few winning MCED test developers." That context was added by Respondents and not agreed to by Dr. Scott Morton. Thus, the proposed finding takes Dr. Scott Morton's testimony completely out of context and should be disregarded.

[redacted]

[redacted]

Additionally, Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial

testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

The proposed finding should also be disregarded because Dr. Katz himself did not conduct any actual assessment of investments in the liquid biopsy or MCED development industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Further, Dr. Katz did not communicate with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)).

Further, there are a number of other "economically logical explanation[s] for the sunk investments" that Dr. Katz did not consider. [redacted]

[redacted]

The proposed finding is also incomplete, misleading, and against the weight of substantial evidence to the extent Respondents suggest that [redacted]

[redacted], this Court should disregard the proposed finding.

940.1 Dr. Scott Morton can cite no evidence to support her speculation that the market is likely to develop that way, or that the purported MCED developers she identifies have such expectations and justify their investments on this basis.

Response to Finding No. 940.1

First, the proposed finding should be wholly disregarded because it lacks any citation to the record and is entirely unsupported. Second, the proposed finding is vague because it does not define "that way," "such expectations," or "this basis." The proposed finding is incomplete and misleading. Respondents mischaracterize Dr. Scott Morton's testimony by adding their own interpretation of the term "bilateral monopoly." Dr. Scott Morton never described "bilateral monopoly" as a market in which "there would be only one or a few winning MCED test developers." That context was added by Respondents and not agreed to by Dr. Scott Morton.

Thus, the proposed finding takes Dr. Scott Morton's testimony completely out of context and should be disregarded.

[redacted]

Moreover, the proposed finding is incomplete and misleading to the extent Respondents suggest that Illumina's acquisition of Grail will incentivize investment in the NGS cancer screening market. [redacted] Therefore, this Court should disregard the proposed finding.

940.2 Further, she separately contended that a bilateral monopoly is unlikely, arguing that, in the but-for world without the merger, Illumina would ensure that there are multiple MCED makers in the market to "lower the profits of the MCED makers and deliver more of it to Illumina." (RX3852 (Scott Morton Dep. at 290).)

Response to Finding No. 940.2

The proposed finding is incomplete and misleading. Respondents mischaracterize Dr. Scott Morton's testimony by adding their own interpretation of the term "bilateral monopoly." Dr. Scott Morton never described "bilateral monopoly" as a market in which "there would be only one or a few winning MCED test developers." That context was added by Respondents and not agreed to by Dr. Scott Morton. Here, Respondents invent additional context for another quote that Dr. Scott Morton used in her deposition that bears no relation to Respondents' fabricated definition of "bilateral monopoly." Thus, the proposed finding takes Dr. Scott Morton's testimony completely out of context and should be disregarded.

[redacted]

[redacted]

940.3 [redacted]

Response to Finding No. 940.3

[redacted]

941. The only economically logical explanation for the sunk investments is that test developers—just as Illumina does—anticipate intensifying upstream competition and being able to switch to alternative platforms if Illumina attempted any opportunistic hold up. (Katz Trial Dep. at 42:17–46:14.)

Response to Finding No. 941

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends

approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

The proposed finding should also be disregarded because Dr. Katz himself did not conduct any actual assessment of investments in the liquid biopsy or MCED development industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Further, Dr. Katz did not communicate

with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)).

Further, there are a number of other "economically logical explanation[s] for the sunk investments" that Dr. Katz did not consider. [redacted]

[redacted]

The proposed finding is also incomplete, misleading, and against the weight of substantial evidence to the extent Respondents suggest that [redacted]

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted]

Therefore, this Court should disregard the proposed finding.

> 941.1 As Dr. Katz explained, "if Complaint Counsel's view of the world and Dr. Scott Morton's view of the world is correct, it would be a risk of really substantial holdup, and these firms just shouldn't be making these investments. But in fact they have made these investments in the past, and . . . those investments are ongoing, and that indicates that in fact they don't believe that they're going to be held up like this. And so . . . their conduct then is inconsistent with Complaint Counsel and Dr. Scott Morton's theory of harm and . . . view of how the economic world operates." (Katz Trial Dep. at 42:17–46:14.)

Response to Finding No. 941.1

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forty to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

The proposed finding should also be disregarded because Dr. Katz himself did not conduct any actual assessment of investments in the liquid biopsy or MCED development industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Further, Dr. Katz did not communicate with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)).

Further, there are a number of other "economically logical explanation[s] for the sunk investments" that Dr. Katz did not consider. [redacted]

[redacted]

[redacted]

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

941.2 Dr. Katz further explained, that inference holds true both for investment activity before Illumina announced its agreement to acquire GRAIL and afterward – it is "really the same economic logic in either case." (RX6004 (Katz Trial Dep. at 46:15–47:3).)

Response to Finding No. 941.2

The proposed finding is vague because it does not define "that inference" or describe what Dr. Katz means by "really the same economic logic in either case." It is misleading to the extent that Dr. Katz suggests that an MCED test developer would consider pursuing an MCED test in the same way if Illumina owns Grail as if it does not. [redacted]

Additionally, Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for

Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

The proposed finding should also be disregarded because Dr. Katz himself did not conduct any actual assessment of investments in the liquid biopsy or MCED development industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Further, Dr. Katz did not communicate with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)).

Further, there are a number of other "economically logical explanation[s] for the sunk investments" that Dr. Katz did not consider. [redacted]

[redacted]

[redacted]

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted] Therefore, this Court should disregard the proposed finding.

942. Professor Scott Morton also claims that investment could have been even greater but for the Transaction, but she offers no evidence of that but-for world, and as Dr. Katz

explained, in all events, "the point still remains that there's substantial investment . . . both before and after the merger, and the existence of that investment is inconsistent with . . . these companies fearing the holdup that would be implied by Dr. Scott Morton's view of the world." (Katz Trial Dep. at 47:21–48:14.)

Response to Finding No. 942

The proposed finding is vague, incomplete, and misleading. It is vague because it does not define "substantial investment" or explain what level of investment Dr. Katz believes would be needed to show that MCED test developers fear being held up by Illumina.

Additionally, Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded.

Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]

[redacted] Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

The proposed finding should also be disregarded because Dr. Katz himself did not conduct any actual assessment of investments in the liquid biopsy or MCED development industry. In particular, Dr. Katz testified at his trial deposition that he did not conduct an assessment of investments in the biotech industry generally or among MCED test developers individually. (RX6004 (Katz Trial Dep. at 140-141)). Further, Dr. Katz did not communicate with any investors as to their rationale for investing in the liquid biopsy and MCED companies. (RX6004 (Katz Trial Dep. at 141)).

Further, there are a number of other "economically logical explanation[s] for the sunk investments" that Dr. Katz did not consider. [redacted]

[redacted]

The proposed finding is also incomplete, misleading, and against the weight of substantial evidence to the extent Respondents suggest that [redacted]

[redacted]

The proposed finding is also misleading to the extent it implies that the pre-Acquisition investment indicates that MCED tests developers have alternatives to Illumina. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

4. **The FTC's Theory Is Belied by the Purchase Price Illumina Paid For GRAIL**

943. [redacted]

Response to Finding No. 943

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3.

Here Respondents cite Dr. Willig in contravention of this Court's Order. This Court should disregard this evidence.

Even if the Court considers this opinion versus fact testimony, the proposed finding still is unsupported given the only source is Dr. Willig's improper expert testimony offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Respondents took advantage of this Court's order by designating Dr. Michael Katz who submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' Proposed Finding should be disregarded in its entirety as improper expert opinion. Given that Respondents have not provided the support of their

substituted expert – Dr. Katz – or any other fact witnesses, this testimony is unsupported and should be disregarded.

Finally, the proposed finding is irrelevant, misleading, and against the weight of the evidence. [redacted]

Finally, as Complaint Counsel explained, the overwhelming weight of the evidence shows that [redacted]. Therefore, this Court should disregard the proposed finding.

944. [redacted]

Response to Finding No. 944

[redacted]

[redacted]

[redacted]

[redacted]

945. [redacted]

Response to Finding No. 945

[redacted]

[redacted]

5. **No Evidence That Switching Costs Would Prevent Switching in Response to sn Attempted Foreclosure Strategy.**

946. Complaint Counsel's contention that switching an MCED test to any alternative NGS platform would be too costly and time-consuming for a test developer to profitably undertake is without empirical support. (*Supra* PFF ¶¶ 790–796.)

Response to Finding No. 946

[redacted]

[redacted]

[redacted]

947. Complaint Counsel also did no analysis of the size of one-time switching costs relative to the benefits of switching in a hypothetical scenario where Illumina has attempted to foreclose an MCED rival. (RX3871 (Willig Expert Report) ¶¶ 46, 48.)

Response to Finding No. 947

[redacted]

[redacted]

[redacted]

947.1 As Dr. Carlton explained, given the magnitude of the potential downstream market—which, if it reaches its full potential, could be in the tens of billions of dollars—it cannot be assumed that even high switching costs would deter test developers from migrating to a rival platform in response to a hypothetical foreclosure strategy, since whether switching costs impede customer defections depends on not only

the magnitude of switching costs but also the benefits from switching. (RX6000 (Carlton Trial Dep. at 38–39).)

Response to Finding No. 947.1

The proposed finding is incomplete, speculative, misleading, and unsupported by the weight of substantial evidence demonstrating that a viable alternative NGS sequencer to Illumina is purely hypothetical at this point, MCED developers have indicated that switching costs are enormous, and there are significant barriers to commercialization of an alternative NGS platform besides the switching costs. In addition, the proposed finding is inherently speculative as Respondents cite only to the paid testimony of Dr. Carlton that is uncorroborated by any ordinary course documents, analysis, or MCED test developers' testimony [redacted] Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Carlton's baseless conjecture, this proposed finding of fact should be disregarded.

[redacted]

948. [redacted] (*Supra* PFF ¶ 791.)

Response to Finding No. 948

[redacted]

[redacted]

[redacted]

948.1 [redacted]

Response to Finding No. 948.1

[redacted]

[redacted]

948.2 Yet neither Complaint Counsel nor Dr. Scott Morton offered any empirical assessment of the *incremental* cost of switching from an Illumina platform to a

third-party platform as compared to the switching cost that would be incurred by a test developer that seeks to upgrade to Illumina's next generation system. (RX3871 (Willig Expert Report) ¶¶ 46, 48.)

Response to Finding No. 948.2

[redacted]

[redacted]

[redacted]

949. Numerous fact witnesses, as well as Dr. Cote, the only technical expert to opine on the matter, testified as to the feasibility of switching, and some Illumina customers have done so for their oncology tests. ([redacted]; Febbo (Illumina) Tr. 4325–26; Aravanis (Illumina) Tr. 1865.)

Response to Finding No. 949

[redacted]

[redacted]

[redacted]

[redacted]

I. Illumina's Prior Vertical Integrations Belie Complaint Counsel's Theory

1. NIPT

950. Illumina's most analogous past vertical acquisition—that of Verinata Health, Inc. ("Verinata")—shows that when Illumina vertically integrates, it continues to support downstream rivals, Illumina helps grow the space, and innovation and competition flourish to the benefit of patients. (RX3864 (Carlton Expert Report) ¶ 162.)

Response to Finding No. 950

[redacted]

[redacted]

951. In February 2013, Illumina acquired Verinata which had developed an NIPT test for fetal chromosomal abnormalities using a blood sample. (RX3337 (Illumina).)

Response to Finding No. 951

Complaint Counsel has no specific response to this proposed finding.

952. At the time it was acquired, Verinata used Illumina sequencers to develop and perform its test, so the acquisition was vertical, just as Illumina's acquisition of GRAIL is vertical. ([redacted] RX3864 (Carlton Expert Report) ¶ 164.)

Response to Finding No. 952

Complaint Counsel has no specific response to this finding.

953. Verinata was one of four companies offering an NIPT test in the U.S.: Sequenom was first to market in 2011, followed by Verinata, Ariosa, and Natera. (PX7089 (Naclerio (Illumina) Dep. at 42); RX3864 (Carlton Expert Report) ¶ 164.)

Response to Finding No. 953

[redacted]

954. As in this case, Illumina was the upstream supplier of sequencing inputs to each of these companies. (RX3864 (Carlton Expert Report) ¶ 164.)

Response to Finding No. 954

[redacted]

955. Illumina was the upstream supplier of sequencing inputs to each of these companies, and, under Dr. Scott Morton's theory in the present case, would have had incentives to raise the costs of rivals to Verinata in order to restrict NIPT competition downstream and divert sales to Verifi. However, a simple examination of the data contradicts such a theory. In contrast to what would be expected had Illumina attempted to raise rivals' costs following its acquisition of Verinata, NIPT output has expanded, Verinata's share has decreased, and Natera's share has increased. (RX3864 (Carlton Expert Report) ¶ 164.)

Response to Finding No. 955

[redacted]

[redacted]

[redacted]

956. Since the acquisition, the number of NIPT tests conducted by Verinata's rivals on Illumina's platforms in the U.S. has increased in each year for which there is available data. (RX3864 (Carlton Expert Report) ¶ 165.)

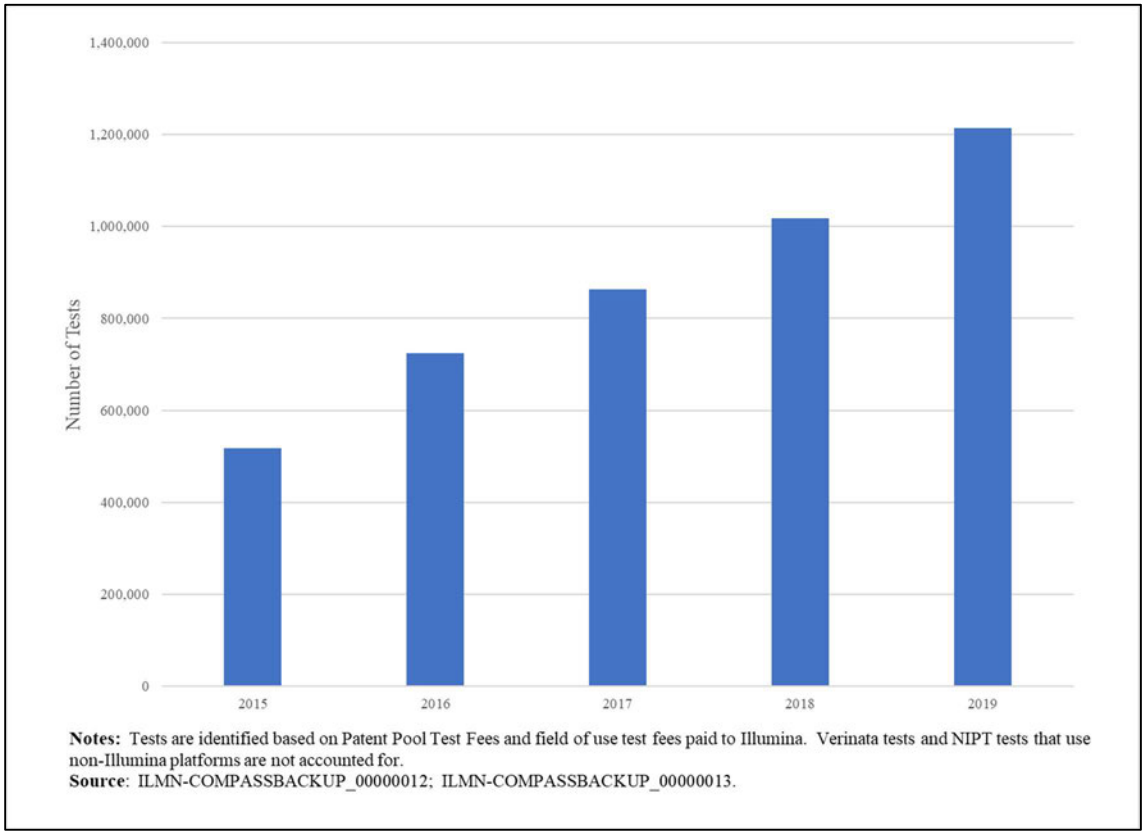
Response to Finding No. 956

[redacted]

[redacted]

956.1 Figure 7 below shows that total NIPT tests conducted by Verinata's rivals on Illumina's sequencing platform have more than doubled between 2015 and 2019.

Figure 7: NIPT Tests Conducted in the U.S. by Verinata Rivals on Illumina's NGS Platform



(RX3864 (Carlton Expert Report), ¶ 165, Figure 3).

Response to Finding No. 956.1

[redacted]

[redacted]

957. In addition to the fact that total output has expanded, Verinata's share of U.S. NIPT sales has decreased. (RX3864 (Carlton Expert Report) ¶ 164.)

Response to Finding No. 957

[redacted]

[redacted]

[redacted]

958. Natera, in contrast, became the market leader after Illumina acquired Verinata, with a consistently high share. (RX3864 (Carlton Expert Report) ¶ 166.)

Response to Finding No. 958

[redacted]

[redacted]

[redacted]

959. Figure 8 below shows the respective shares of U.S. NIPT providers who use the Illumina NGS platform:

(RX3864 (Carlton Expert Report) Figure 4).

Response to Finding No. 959

[redacted]

[redacted]

960. Natera has remained the market leader throughout with a consistently high share, while Verinata's share has fallen more than 50%. (RX3864 (Carlton Expert Report) ¶ 162.)

Response to Finding No. 960

[redacted]

[redacted]

[redacted]

[redacted]

961. [redacted]

Response to Finding No. 961

[redacted]

[redacted]

[redacted]

962. Furthermore, there has been a steady stream of new entry and substantial investment into NIPT testing in the U.S. since the Verinata acquisition, indicating that downstream competitors to Verinata are not concerned that Illumina will act anticompetitively, and that Illumina has not in fact acted anticompetitively, in the NIPT space. (RX3589 (Illumina); RX3864 (Carlton Expert Report) ¶ 162.)

Response to Finding No. 962

[redacted]

[redacted]

962.1 Figure 9 below shows the NIPT providers in the U.S. that use Illumina's platform and which providers entered or exited each year (other providers, using other sequencing platforms, may exist). (RX3864 (Carlton Expert Report) ¶ 167.)

(RX3864 (Carlton Expert Report) at Figure 5.)

Response to Finding No. 962.1

[redacted]

962.2 Since Illumina acquired Verinata, seven new NIPT providers have launched using the Illumina platform and two have exited (with one customer switching to a non-Illumina platform and one customer being acquired). (RX3864 (Carlton Expert Report) ¶ 167.)

Response to Finding No. 962.2

[redacted]

[redacted]

962.3 Overall, the number of NIPT providers on Illumina's platform has more than doubled. Such entry (and the significant investment required to pull it off) is

inconsistent with the claim that Illumina has disadvantaged downstream rivals, or that the fear that it would do so has impeded innovation in the NIPT space. (RX3864 (Carlton Expert Report) ¶ 167.)

Response to Finding No. 962.3

[redacted]

[redacted]

963. A number of fact witnesses confirmed what the economic evidence alone starkly demonstrates: that Illumina's entry into NIPT via a vertical transaction was decidedly procompetitive:

Response to Finding No. 963

Complaint Counsel objects to the proposed finding because it is unsupported, as it does not cite to any evidence of record. This Court should disregard the proposed finding.

> 963.1 Dr. Aravanis testified that since the Verinata acquisition, "the cost of noninvasive prenatal testing has decreased by over 90 percent"; "[t]he number of tests performed has gone up by a factor of a hundred"; "[t]he number of companies offering noninvasive prenatal tests has . . . increased significantly"; and "[t]he coverage of patients for noninvasive prenatal testing has increased by at least 100 million women." (Aravanis (Illumina) Tr. 1933–34.)

Response to Finding No. 963.1

Complaint Counsel objects to the proposed finding because it is misleading, relies on self-serving testimony, and is contrary to the weight of the evidence.

The proposed finding is misleading because the decrease in the cost of NIPT is unrelated to Illumina's acquisition of NIPT. To the contrary, Illumina acquired Verinata so that it could impose a "price floor" that would put a stop to "irrational pricing" by low-cost NIPT providers and prevent further erosion of Illumina's profits. (CCFF ¶ 4115); (PX2076 at 003 (Illumina, Strategic Approach to Shaping the NIPT Market, Mar. 13, 2013)); (PX7060 (Naclerio (Illumina)

IHT at 65)). The proposed finding is likewise misleading because use and payer adoption of NIPT was increasing prior to Illumina's acquisition of Verinata. For example, Illumina's deal model for the acquisition of Verinata assumed that the cost of sequencing for NIPT would decrease by 20% per year. (PX2428 at 019, 024 (Project Positano, Illumina, Dec. 27, 2012)). Likewise, Illumina's vertical integration did not increase payer adoption. [redacted]

The proposed finding relies solely upon the self-serving testimony of Illumina Chief Technology Officer Alex Aravanis to claim that Illumina's acquisition of Verinata was beneficial for NIPT. [redacted] In light of the overwhelming weight of the evidence, which directly contradicts this proposed finding, which is based solely on the self-serving testimony of Illumina's CTO Alex Aravanis, should be disregarded.

963.2 Mr. deSouza testified that in NIPT, Illumina makes "eight times as much revenue selling sequencers and consumables to companies that compete with our test than we do from our own test", which is one of multiple factors driving Illumina's incentives to support all NIPT customers, including its downstream rivals, as the economic evidence demonstrates Illumina has done. (deSouza (Illumina) Tr. 2393–94, 2378–79.)

Response to Finding No. 963.2

Complaint Counsel objects to the proposed finding because it is misleading, relies on self-serving testimony, and is contrary to the weight of the evidence.

[redacted] Moreover, it is grossly misleading to claim that Illumina "supports" all NIPT customers. After acquiring Verinata, Illumina engaged in a scorched earth campaign against its lowest-priced NIPT customers, adopting a strategy to "[c]reate a cost structure for Natera that they can't sustain or introduces a reasonable price floor" and "[l]ock in Ariosa to license terms in order to ensure [a m]arket price floor." (PX2076 at 003 (Illumina, Strategic approach to shaping the NIPT market, Mar. 13, 2013)). As a result of Illumina's conduct, [redacted]; PX2274 at 006 (Strategic Approach to Increasing Value in NIPT Testing, Illumina, Mar. 20, 2013)). In light of the overwhelming weight of the evidence, which directly contradicts this proposed finding, which is based solely on the self-serving testimony of Illumina's CEO Francis deSouza, should be disregarded.

963.3 Mr. deSouza further noted that investment in NIPT increased substantially after Illumina entered that market through the Verinata acquisition. (deSouza (Illumina) Tr. 2392–93.)

Response to Finding No. 963.3

Complaint Counsel objects to the proposed finding because it is misleading, relies on self-serving testimony, and is contrary to the weight of the evidence.

The proposed finding is misleading because it suggests that Illumina's acquisition of Verinata caused the increase in investment in NIPT. This is contradicted by contemporaneous Illumina documents, which projected a massive increase in NIPT testing and payer adoption absent the acquisition of Verinata. (PX2428 at 004 (Project Positano, Illumina, Dec. 27, 2012); *see also* (PX2760 at 005 (Inside Sales Training NIPT, Illumina, Mar. 23, 2016 (showing a timeline of payer adoption with an increase of over 100 million covered lives between 2011 and the acquisition of Verinata in 2013)). Moreover, the relevant inquiry is to compare the level of investment today with what the level of investment *would have been* absent the Verinata acquisition. (Complaint Counsel's Post-Trial Reply Brief § III.F.1.c). Finally, it is improbable that Illumina's acquisition of Verinata drove increased investment in NIPT because Illumina adopted a strategy of limiting participation in NIPT to "few players at economics close to Verinata." (PX2438 at 001, 004 (E-mail from N. Naclerio, Illumina, to N. Donoghoe, McKinsey, Mar. 11, 2013); *see also* (PX2076 at 003 (Illumina, Strategic approach to shaping the NIPT market, Mar. 13, 2013); [redacted]). [redacted] Illumina filed no fewer than four IP lawsuits against its customers that also compete with its NIPT test, and [redacted]; *see also Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:18-cv-02847 (N.D. Cal. filed May 15, 2018*); Illumina, Inc. v. Natera, Inc.*, No. 3:18-cv-01662 (N.D. Cal. filed Mar. 16,

2018); *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:15-cv-02216 (N.D. Cal. filed May 18, 2015); *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:14-cv-01921 (N.D. Cal. filed Apr. 25, 2014). In light of the overwhelming weight of the evidence, which directly contradicts this proposed finding, which is based solely on the self-serving testimony of Illumina's CEO Francis deSouza, should be disregarded.

963.4 Invitae, an Illumina NIPT (and oncology) customer, has attested through a sworn declaration from its CEO that Illumina has been a "partner[]" and a "leader[]" in achieving payor coverage for NIPT tests for a broader set of patients, which has benefitted all market participants in that space. (RX1100 (George (Invitae) Decl.¶ 10).)

Response to Finding No. 963.4

Complaint Counsel objects to the proposed finding as incomplete and misleading.

[redacted] Illumina filed no fewer than four IP lawsuits against its customers that also compete with its NIPT test, and [redacted]; *see also Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:18-cv-02847 (N.D. Cal. filed May 15, 2018*); Illumina, Inc. v. Natera, Inc.*, No. 3:18-cv-01662 (N.D. Cal. filed Mar. 16, 2018);

Illumina, Inc. v. Ariosa Diagnostics, Inc., No. 3:15-cv-02216 (N.D. Cal. filed May 18, 2015); *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:14-cv-01921 (N.D. Cal. filed Apr. 25, 2014).

This proposed finding is misleading because Illumina's vertical integration did not cause an increase in payer adoption. [redacted]

Likewise, Illumina's own documents show that payer adoption was already occurring at a rapid rate at the time that Illumina acquired Verinata. (PX2760 at 005 (Inside Sales Training NIPT, Illumina, Mar. 23, 2016 (showing a timeline of payer adoption with an increase of over 100 million covered lives between 2011 and the acquisition of Verinata in 2013)). Likewise, Illumina's presentation to its board of directors about the Verinata acquisition shows that rapid payer adoption was already underway and expected to intensify independently of the acquisition. (PX2428 at 004 (Project Positano, Illumina, Dec. 27, 2012).

2. **Therapy Selection**

964. Illumina has also vertically integrated into therapy selection through organic development of its therapy selection test, TSO500. (Leite (Illumina/InterVenn) Tr. 2075–76; Aravanis (Illumina) Tr. 1952.)

Response to Finding No. 964

The proposed finding is vague because it does not define "organic development." Therefore, this Court should disregard the proposed finding.

964.1 [redacted] As a result, therapy selection test developers compete with each other to convince pharmaceutical companies—who market the therapies—to partner with them for a particular therapy. (Goswami (Illumina) Tr. 3184.)

Response to Finding No. 964.1

[redacted]

965. Although Complaint Counsel claims Illumina's vertical integration into therapy selection resulted in Illumina raising rivals' costs and harming competition, the evidence is to the contrary. (PFF ¶¶ 966–973.)

Response to Finding No. 965

The proposed finding is unsupported because no evidence is cited for this "fact."

Therefore, this Court should disregard the proposed finding.

966. Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors to Illumina are developing in-vitro diagnostic ("IVD") tests that will compete with Illumina's own TSO500 therapy selection test. (Goswami (Illumina) Tr. 3202–03.)

Response to Finding No. 966

The proposed finding is vague, misleading, and against the weight of the evidence, and the Court should therefore disregard Respondents' proposed finding. The proposed finding is vague, because Respondents fail to define the terms "numerous" and "formidable."

The proposed finding is misleading and against the weight of the evidence. The proposed finding is generally misleading, insofar as it implies that, after previous vertical acquisitions involving therapy selection tests, Illumina fairly engaged with its downstream competitors. [redacted]

PUBLIC

[redacted]

[redacted]); [redacted]

[redacted]

[redacted]

Rather than referencing evidence or testimony produced by Roche or PGDx, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

967. Illumina provides customer support to its therapy selection rivals and there is increasing investment and innovation in this space in recent years. (Goswami (Illumina) Tr. 3202–03.)

Response to Finding No. 967

The proposed finding is misleading, against the weight of the evidence, supported only

by self-serving testimony, and vague, and this Court should therefore disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence. The proposed finding is misleading, insofar as it implies that "increasing investment and innovation" in the market for therapy selection tests has anything to do with Illumina. [redacted]

Moreover, rather than referencing documents from Illumina's downstream competitors in the therapy selection test market, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is vague. Respondents fail to define or quantify the terms "increasing investment and innovation" and "recent years."

> 967.1 As Dr. Joydeep Goswami, who oversees Illumina's IVD agreements, testified, "test developers are investing in developing IVD kits under the terms of [Illumina's] IVD agreements", and far from diminishing innovation in kitted oncology tests, Illumina's IVD program "spurs innovation" because test developers can "just tap

into a network of instruments that is available globally that can run the assay that they're providing, so it's a huge saving of investment on their side and time on their side and resources on their side." (Goswami (Illumina) Tr. 3217–18.)

Response to Finding No. 967.1

The proposed finding is misleading, against the weight of the evidence, supported only by self-serving testimony, improper, and vague, and this Court should disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence, which clearly shows that Illumina has made every effort to use its control over IVD rights to impair its customers' ability to innovate. [redacted]

[redacted]

Moreover, rather than referencing documents from Illumina's downstream competitors in the therapy selection test market, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Further, the proposed finding is improper and vague. Respondents cite to one of their own executives to about the investment strategies of downstream competitors, several of whom provided evidence in this litigation. It's unclear why—and indeed unlikely that—Mr. Goswami has foundation to discuss the investment strategies or what is a "huge saving of investment . . . and time . . . and resources" of Illumina's downstream competitors simply because he "oversees Illumina's IVD agreements." Therefore, this Court should disregard the proposed finding.

968. From a strategic perspective, Illumina views more test developers using its IVD platform (which it refers to as "IVD partners") as a positive regardless of whether those partners compete with Illumina's TSO500 test. (Goswami (Illumina) Tr. 3201–02, 3217–18.)

Response to Finding No. 968

The proposed finding is vague, misleading, and against the weight of the evidence, and the Court should therefore disregard Respondents' proposed finding. The proposed finding is vague because Respondents fail to define the terms "strategic perspective," "test developers," and "a positive."

[redacted]

[redacted]

[redacted]

Rather than referencing evidence or testimony produced by "test developers using its IVD platform," Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 968.1 As Mr. deSouza testified, "[e]ven in markets where we have our own test, so noninvasive prenatal testing, for example, or cancer therapy selection, . . . or genetic disease diagnosis – even in those markets, we make significantly more money by selling sequencers and consumables to companies that compete with our test than we do from our own test." (deSouza (Illumina) Tr. 2378–79).

Response to Finding No. 968.1

The proposed finding is misleading for two reasons. First, the proposed finding is misleading insofar as it implies that, as a result of the Transaction, Illumina will not be incentivized to disadvantage Grail's competitors because in Illumina's other vertically integrated markets, "[Illumina] make[s] significantly more money by selling sequencers and consumables . . . than [Illumina] do[es] from [its] own test." This may simply indicate that Illumina is bad at selling its own tests, or that Illumina earns smaller margins on their other vertically integrated tests than they do on sequencers and consumables, or, perhaps, that Illumina is charging downstream competitors more for sequencers and consumables. Moreover, it is unclear how Mr. deSouza's claims regarding Illumina's other vertically integrated markets have any bearing on Illumina's behavior or incentives in the MCED test market. In any event, insofar as Respondents imply that Illumina will not disadvantage Grail's downstream rivals, such an implication is not supported by the cited testimony, nor is it supported by the weight of the evidence, which demonstrates that, as a result of the transaction, Illumina has a strong incentive to harm Grail's rivals at both the development and commercialization stages. (*See, e.g.*, Complaint Counsel's Post-Trial Brief Sec. II(E)(1)(b)).

Second, the proposed finding is misleading, in that it is unsupported by Illumina's ordinary course documents. [redacted]

[redacted] This proposed finding is therefore misleading and should be disregarded by this Court.

Rather than referencing evidence or testimony produced by "test developers using its IVD platform," Respondents cite to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 968.2 As Mr. deSouza testified, "[i]n cancer therapy selection, we make 14 times as much money selling sequencers and consumables to companies that compete with our test than we do from our own test", and that dynamic drives Illumina's strategy which "has been consistently to open up a market and then enable lots of players to serve that market, each with their own different approach, because we believe that maximizes the opportunity in the market." (deSouza (Illumina) Tr. 2379–80).

Response to Finding No. 968.2

The proposed finding is misleading for two reasons. First, the proposed finding is misleading insofar as it implies that, as a result of the Transaction, Illumina will not be incentivized to disadvantage Grail's competitors because in cancer therapy selection, "[Illumina]

make[s] 14 times as much money selling sequencers and consumables to companies that compete with [Illumina's] test than we do from [Illumina's] own test." This may simply indicate that Illumina is bad at selling its own tests, or that Illumina earns smaller margins on their therapy selections tests than they do on sequencers and consumables, or, perhaps, that Illumina is charging downstream competitors more for sequencers and consumables. Moreover, it is unclear how Mr. deSouza's claims regarding Illumina's therapy selection tests have any bearing on Illumina's behavior or incentives in the MCED test market. In any event, insofar as Respondents imply that Illumina will not disadvantage Grail's downstream rivals, such an implication is not supported by the cited testimony, nor is it supported by the weight of the evidence, which demonstrates that, as a result of the transaction, Illumina has a strong incentive to harm Grail's rivals at both the development and commercialization stages. (*See, e.g.*, Complaint Counsel's Post-Trial Brief Sec. II(E)(1)(b)).

Second, the proposed finding is misleading, in that it is unsupported by Illumina's ordinary course documents. [redacted]

[redacted]

This proposed finding is therefore misleading and should be disregarded by this Court.

Rather than referencing evidence or testimony produced by "test developers using its IVD platform," Respondents cite to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

969. [redacted]

Response to Finding No. 969

[redacted]

[redacted]

969.1 [redacted]

Response to Finding No. 969.1

Complaint Counsel has no specific response to this proposed finding.

969.2 [redacted]

Response to Finding No. 969.2

Complaint Counsel has no specific response to this proposed finding.

969.3 However, Illumina has in fact signed IVD agreements in therapy selection—including with TMB rights—with anyone that has pursued such rights, and test developers are investing in developing and seeking regulatory approvals for tests under those agreements. (Leite (Illumina/InterVenn) Tr. 2141–3219; Goswami (Illumina) Tr. 3218.)

Response to Finding No. 969.3

The proposed finding is misleading, and against the weight of the evidence, and the Court should therefore disregard Respondents' proposed finding. The proposed finding is misleading and against the weight of the evidence, which demonstrates that Illumina disadvantaged downstream companies because Illumina viewed those companies as rivals. That Illumina has, at some point down the road, "signed IVD agreements . . . with anyone" is besides the point.

[redacted]

970. Complaint Counsel places particular weight on Illumina's interactions with PGDx; however, the evidence refutes Complaint Counsel's claims concerning these interactions:

Response to Finding No. 970

The proposed finding is unsupported because no evidence is cited for this "fact."

970.1 [redacted]

Response to Finding No. 970.1

[redacted]

970.2 [redacted]

Response to Finding No. 970.2

[redacted]

[redacted]

970.3 [redacted]

Response to Finding No. 970.3

[redacted]

[redacted]

970.4 [redacted]

Response to Finding No. 970.4

[redacted]

[redacted]

970.5 [redacted]

[redacted]

Response to Finding No. 970.5

[redacted]

971. Complaint Counsel also places particular weight on Illumina's interactions with Roche; however, the evidence refutes Complaint Counsel's claims concerning these interactions as well:

Response to Finding No. 971

The proposed finding is unsupported because no evidence is cited for this "fact."

Therefore, this Court should disregard the proposed finding.

971.1 [redacted]

Response to Finding No. 971.1

[redacted]

[redacted]

971.2 [redacted]

Response to Finding No. 971.2

[redacted]

[redacted]

971.3 [redacted]

Response to Finding No. 971.3

[redacted]

[redacted]

971.3.1 [redacted]

Response to Finding No. 971.3.1

[redacted]

[redacted]

971.4 [redacted]

Response to Finding No. 971.4

[redacted]

[redacted]

971.5 [redacted]

Response to Finding No. 971.5

[redacted]

[redacted]

971.6 [redacted]

Response to Finding No. 971.6

[redacted]

[redacted]

972. Dr. Scott Morton concluded that the events in the therapy selection space show that Illumina has engaged in foreclosure where it is vertically integrated, yet she does no actual analysis of the therapy selection space and the competitive impact of Illumina's vertical integration into therapy selection. RX6000 (Carlton Trial Dep. at 201).)

Response to Finding No. 972

Respondents confusingly cite to their own experts' trial deposition to support a factual proposition regarding the conclusions of Complaint Counsel's expert. [redacted] Moreover, Respondents mischaracterize their own expert's testimony. Dr. Carlton testified that he has not "seen . . . Dr. Scott Morton analyze" what Dr. Carlton considers to be the relevant question. RX6000 (Carlton Trial Dep. at 200-201). It is not true that Dr. Carlton testified that Dr. Scott Morton "does no actual analysis," as Respondents propose in this finding.

The proposed finding is vague because Respondents fail to define the terms "the events," "actual analysis," and "competitive impact." **Therefo**re, this Court should disregard the proposed finding.

> 972.1 As Dr. Carlton explained, if one were to do an actual economic analysis of the impact of Illumina's vertical integration into therapy selection, "the relevant question" would have to be "what's the but-for world", meaning, "was there a benefit from Illumina being vertically integrated into therapy selection and selling to Roche compared to not having Illumina in therapy selection". (RX6000 (Carlton Trial Dep. at 201).)

Response to Finding No. 972.1

The proposed finding is vague. Respondents' fail to define the terms "actual economic analysis," "relevant," and "benefit."

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding cites only to Dr. Carlton's trial deposition testimony, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Carlton's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding. Therefore this Court should disregard Respondents' proposed finding.

> 972.2 Yet that is not what Dr. Scott Morton did by a long shot—"she pays no attention to the benefit of vertical integration of Illumina into therapy selection." (RX6000 (Carlton Trial Dep. at 201).)

Response to Finding No. 972.2

The proposed finding is vague. Respondents fail to define the terms "that" or "long shot." The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' proposed finding cites only to Dr. Carlton's trial deposition testimony, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Carlton's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding. Therefore this Court should disregard Respondents' proposed finding.

972.3 [redacted]

Response to Finding No. 972.3

[redacted]

972.4 [redacted]

Response to Finding No. 972.4

[redacted]

972.5 [redacted]

Response to Finding No. 972.5

[redacted]

972.6 [redacted]

Response to Finding No. 972.6

Complaint Counsel has no specific response to this proposed finding.

972.7 [redacted]

Response to Finding No. 972.7

[redacted]

[redacted]

972.8 [redacted]

Response to Finding No. 972.8

[redacted]

[redacted]

973. In licensing IVD rights in a field of use and charging fees for those rights, Illumina has simply followed market practice in the industry.

Response to Finding No. 973

The proposed finding is unsupported because no evidence is cited for this "fact."

Therefore, this Court should disregard the proposed finding.

973.1 [redacted]

Response to Finding No. 973.1

[redacted]

[redacted]

973.2 [redacted]

Response to Finding No. 973.2

[redacted]

3. **Population Genomics and Helix**

974. Several of the exhibits offered by Complaint Counsel relate to Illumina's spinout of Helix, a population genomics company that competes with providers such as Ancestry.com. (*See, e.g.,* PX7077 (Chahine (Helio) Dep.); [redacted]; PX 2420–2421 (Illumina); [redacted]

Response to Finding No. 974

[redacted]

975. Yet, Illumina's conduct in connection with the formation and spinout of Helix was recognized, even by Helix's competitors, as "fantastic". (PX7077 (Chahine (Helio) Dep. at 57) ("Illumina was -- you know, was and continues to be a fantastic partner to -- to Ancestry.").)

Response to Finding No. 975

The proposed finding is misleading. As Respondents include within their citation, Dr. Chahine's quoted testimony concerned Ancestry.com. He was, in no way commenting on "the

formation and spinout of Helix" by Illumina. This proposed finding is just flatly incorrect and should be disregarded by this Court.

976. [redacted]

Response to Finding No. 976

[redacted]

977. [redacted]

Response to Finding No. 977

[redacted]

[redacted]

977.1 [redacted]

Response to Finding No. 977.1

[redacted]

[redacted]

977.2 [redacted]

Response to Finding No. 977.2

[redacted]

[redacted]

977.3 [redacted]

Response to Finding No. 977.3

[redacted]

[redacted]

977.4 [redacted]

Response to Finding No. 977.4

[redacted]

978. [redacted]

Response to Finding No. 978

[redacted]

J. GRAIL Formation and Spinout

979. Any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition.

Response to Finding No. 979

The proposed finding is unsupported because no evidence is cited for this "fact." Therefore, this Court should disregard the proposed finding.

980. At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep discounting, it would be impossible for GRAIL to develop a cancer screening test:

Response to Finding No. 980

The proposed finding is uncited, improper, vague, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' fail to provide any specific reference in support of their proposed findings, in direct contravention of this Court's Order. The proposed finding is also vague, as Respondents fail to

define the terms "moonshot concept" or "deep discounting." Therefore, this Court should disregard the proposed finding.

> 980.1 As Dr. Aravanis, who helped form GRAIL, testified, the industry reaction to the formation of GRAIL was "very, very skeptical" because the conventional wisdom was that, while GRAIL's mission was "noble", "it will be very hard, may not work at a scientific level and, even if it did, will take a very long time and be very challenging from a cost and clinical development" perspective. (Aravanis (Illumina) Tr. 1873–74.)

Response to Finding No. 980.1

The proposed finding is unreliable and vague, and this Court should therefore disregard Respondents' proposed evidence. The proposed finding is unreliable because Dr. Aravanis does not have foundation to speak to the "industry reaction" to Illumina's formation of Grail. Moreover, the proposed finding is vague, in that Respondents fail to define the terms "industry reaction," "very, very skeptical," "conventional wisdom," "noble," "very hard," "may not work," "very long time," and "very challenging."

> 980.1.1 As Dr. Nick Naclerio, Illumina's Senior Vice President of Corporate and Venture Development at the time of GRAIL's formation, testified, "I think at the time most of the other companies in the field thought—and what they told their investors was Illumina is kind of crazy to go after this [asymptomatic] pan cancer screening, that we're going after more reasonable commercial applications, like screening high-risk people or minimal residual disease or other things like that, and, you know, Illumina is kind of going after this crazy thing. Well, it's kind of good for the field, but I think most people thought it was a science project. (PX7089 (Naclerio (Illumina) Dep. at 276).)

Response to Finding No. 980.1.1

The proposed finding is unreliable, vague, and should be disregarded by this Court. The proposed finding is unreliable because Dr. Naclerio does not have foundation to speak to what "most of the other companies in the field thought—and what they told their investors." In particular, Dr. Naclerio has no basis to opine regarding the "thoughts" of other companies, and Respondents should not be permitted to pass his own opinions on other companies' "thoughts" as facts. Moreover, the proposed finding is vague. Respondents fail to define the terms "most of

the other companies," "kind of crazy," "we're," "kind of good for the field," "a science project." This Court should disregard the proposed finding.

> 980.2 As Illumina's contemporaneous internal documents noted, at the time, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the segment, Illumina "felt an imperative to organize an entity" focused on that moon-shot mission. (RX1088 (Illumina) at 7; (Flatley (Illumina) Dep. at 111–12).)

Response to Finding No. 980.2

The proposed finding is misleading, unsupported, and vague, and this Court should disregard Respondents' proposed evidence. The proposed finding is misleading, insofar as it implies that Illumina created Grail to "accelerate growth of the segment." Such an inference is against the weight of the evidence. (*See generally*, CCFF I.A.2-3). Specifically, by forming Grail, Illumina assessed that it could "capitalize on [the] screening market years earlier AND own a substantial portion of the value created." (CCFF ¶ 34). After spinning off Grail, Illumina provided Grail with advantages relative to the "segment." While Illumina controlled Grail, Illumina provided Grail with "forward pricing." (CCFF ¶ 30). "Forward pricing" meant that Illumina charged Grail what Illumina expected its prices to be a number of years in the future. (CCFF ¶ 30). The impact of providing forward pricing to Grail was that Illumina gave Grail discounts on reagents. (CCFF ¶ 30). In an internal 2015 document, Illumina identified preferential, low-cost access to Illumina sequencing technology as a competitive advantage for Grail: Grail "is uniquely positioned to pioneer this field . . . at depths that are cost prohibitive for others." (CCFF ¶ 36). Illumina initially offered a 75 percent discount on Illumina products for use in Grail's "Foundational Study and commercial screening." (CCFF ¶ 37).

The proposed finding is unsupported because the finding claims that "internal documents" note Illumina's belief. Yet Respondents cite to only one internal document in support of this claim. The proposed finding is vague. Respondents fail to define the terms

"responsibly," "economically," "growth of the segment," and "moon-shot mission."

Further, the proposed finding is in contravention of this Court's Order, which requires that "when citing to exhibits, the parties shall identify the document by the PX or RX number[.]" (Order on Post-Trial Findings at 3). Here, Respondents fail to provide a PX or RX number for the second source of their string citation. Therefore, this Court should disregard the proposed finding.

> 980.3 In other words, there was no one else pursuing the goal that Illumina set GRAIL on a path to pursue, and any special pricing at that time was not designed to put rivals at a disadvantage—there were no rivals, and the goal was in fact to *accelerate* the development of the cancer screening space by years, which would benefit others who might seek to invest in the space. (Aravanis (Illumina) Tr. 1873–74; RX1088 (Illumina) at 7.))

Response to Finding No. 980.3

The proposed finding is misleading, unsupported, and vague, and this Court should disregard Respondents' proposed evidence. The proposed finding is misleading, insofar as it implies that Illumina created Grail to "accelerate growth of the segment." Such an inference is against the weight of the evidence. (*See* generally, CCFF I.A.2-3). Specifically, by forming Grail, Illumina assessed that it could "capitalize on [the] screening market years earlier AND own a substantial portion of the value created." (CCFF ¶ 34). After spinning off Grail, Illumina provided Grail with advantages relative to the "segment." While Illumina controlled Grail, Illumina provided Grail with "forward pricing." (CCFF ¶ 30). "Forward pricing" meant that Illumina charged Grail what Illumina expected its prices to be a number of years in the future. (CCFF ¶ 30). The impact of providing forward pricing to Grail was that Illumina gave Grail discounts on reagents. (CCFF ¶ 30). In an internal 2015 document, Illumina identified preferential, low-cost access to Illumina sequencing technology as a competitive advantage for Grail: Grail "is uniquely positioned to pioneer this field . . . at depths that are cost prohibitive for

others." (CCFF ¶ 36). Illumina initially offered a 75 percent discount on Illumina products for use in Grail's "Foundational Study and commercial screening." (CCFF ¶ 37). Therefore, this Court should disregard the proposed finding.

> 980.4 As Dr. Naclerio put it: "Illumina really went out of its way to create something that we thought no one else was going to do. . . . [I]f you look at the original agreements around what GRAIL can and can't do . . . we designed it specifically so that they wouldn't be competing with any other near-term products of any of the other companies we've talked about. It was really meant to be bringing in something that might someday be possible in the future by years. And I think if you look at the original GRAIL business plan, they talk about how this would save tens of thousands of lives by having this available sooner." (PX7089 (Naclerio (Illumina) Dep. at 275–76).)

Response to Finding No. 980.4

The proposed finding is vague, unreliable, self-serving testimony. It is vague because Respondents do not explain how Illumina "went out of its way" nor do Respondents define what the phrase "something that might someday be possible in the future by years" means. It is unreliable because it relies solely upon the self-serving testimony of Illumina's executive Mr. Naclerio. Further, Respondents asked an improper vague question to elicit this response. As such this statement is unclear, unreliable and should be disregarded and given limited weight.

981. These considerations from the time of GRAIL's formation no longer exist for many reasons, including because (i) the cost of sequencing has come down since 2016 (*supra* PFF ¶ 22); and (ii) Illumina's assumptions about the volume of sequencing required to develop a cancer screening test were significantly higher than what is actually required (Flatley (Illumina) Dep. at 118–20).)

Response to Finding No. 981

The proposed finding is vague. Respondents fail to define the terms "these considerations," "many reasons," "come down," and "significantly higher." Therefore, this Court should disregard the proposed finding.

VII. COMPLAINT COUNSEL ERRS IN DISMISSING THE OPEN OFFER

A. Background on Supply Agreements and Illumina's Commercial Operations Organization

982. Illumina's products and services serve customers in a wide range of markets, enabling the adoption of genomic solutions in research and clinical settings. (PX0061 (Illumina) at 5.)

Response to Finding No. 982

The proposed finding is vague because the terms "genomic solutions" and "research and clinical settings" are ambiguous and undefined. Moreover, the proposed finding is vague as to the meaning of "enabling the adoption of genomics solutions." Therefore, this Court should disregard the proposed finding.

982.1 Illumina's customers include genomic research centers, academic institutions, government laboratories and hospitals. (PX0061 (Illumina) at 5.) They also include pharmaceutical companies, biotechnology companies, commercial molecular diagnostic laboratories and consumer genomics companies. (PX0061 (Illumina) at 5.)

Response to Finding No. 982.1

Complaint Counsel has no specific response to this proposed finding.

983. Illumina's commercial operations organization for the Americas region is responsible for customer-facing activities to drive both revenue and customer success for all of Illumina's current and potential customers in the region. (Berry (Illumina) Tr. 833–34.) The team consists of about 700 people and is led by Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Commercial Team. (Berry (Illumina) Tr. 833.)

Response to Finding No. 983

[redacted]

[redacted]

983.1 The sales organization is responsible for ongoing customer interactions in the normal course of business, including prospecting and acquiring new customers, managing existing customers and providing post-sale support. (Berry (Illumina) Tr. 834.)

Response to Finding No. 983.1

Complaint Counsel has no specific response to this proposed finding.

983.2 The commercial team is highly focused on driving customer success because a key part of Illumina's value proposition and ability to drive growth is customer satisfaction. (Berry (Illumina) Tr. 835.)

Response to Finding No. 983.2

[redacted]

[redacted]

[redacted]

[redacted]

983.3 Illumina validates customer satisfaction through surveys and other methods for collecting feedback. (Berry (Illumina) Tr. 837–38.)

Response to Finding No. 983.3

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, Nicole Berry, and does not include any evidence or support from any of Illumina's customers. Moreover, the proposed finding is misleading to the extent that it implies Illumina prioritizes customer satisfaction over making as much money as possible. First and foremost, Illumina is a public company that cares about maximizing its revenue for its shareholders above all else. [redacted] When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (deSouza (Illumina) Tr. 2220).

Second, the weight of the evidence shows that Illumina's reputation among its customers is already poor. [redacted]

[redacted].

Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted].

Given Illumina's poor reputation, customers are careful in their dealings with Illumina. As [redacted]. Singlera's Dr. Gao similarly testified that when working with Illumina its "their [Illumina's] way is my way or the highway. If you gave [Illumina] that profit margin, well, [Illumina] – you know, [Illumina] can allow you to survive. If not, you just die." (PX7042 (Gao (Singlera) IHT at 87-88)).

Invitae's Mr. Stahl and Singlera's Mr. Gao both testified that Illumina is the 800-pound gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2951; PX7044

(Stahl (Invitae) IHT at 49-50); *see also* Gao (Singlera) Tr. 2947-48). Illumina "dominate[s]" the industry. (PX7044 (Stahl (Invitae) IHT at 49-50)). Therefore, this Court should disregard the proposed finding.

983.4 Since acquiring GRAIL, Illumina has not changed the way its commercial team (or Illumina as a whole) will interact with customers because Illumina's goal of unlocking the power of the genome can be accomplished only by making it easy for customers to access Illumina's technology. (Berry (Illumina) Tr. 838–39.)

Response to Finding No. 983.4

[redacted]

[redacted]

[redacted]

983.5 After the transaction, Illumina's core commercial sales team will not have any role in selling GRAIL's products. (Berry (Illumina) Tr. 839.)

Response to Finding No. 983.5

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of the Americas commercial region, Nicole Berry. Moreover, the proposed finding is incomplete as it is against the weight of the evidence, and incorrect based on Ms. Berry's other testimony. Ms. Berry testified that the new account manager in charge of Grail's account ultimately reports to Ms. Berry. (CCFF ¶¶ 4756-57).

[redacted] Therefore, this Court should disregard the proposed finding.

984. Existing Illumina customers that do not have a pricing agreement begin the process of purchasing a sequencing instrument or core consumable by initiating a conversation with their Illumina sales representative. (Berry (Illumina) Tr. 840.)

Response to Finding No. 984

The proposed finding is misleading to the extent it implies that Illumina customers without a pricing agreement always begin the process of purchasing a sequencing instrument or core consumables by conversing with an Illumina sales representative. Ms. Berry's own trial testimony states that if a customer does not "have a pricing agreement, they *would likely* initiate a conversation with their Illumina sales representative…" (Berry (Illumina) Tr. 840) (emphasis added). Therefore, this Court should disregard the proposed finding.

984.1 The representative ensures that the customer purchases the Illumina products best fit for their needs and then provides a price quote. (Berry (Illumina) Tr. 840–41.) The customer then executes a purchase order consistent with the price quote. (Berry (Illumina) Tr. 841.)

Response to Finding No. 984.1

Complaint Counsel has no specific response to this proposed finding.

985. Sometimes, Illumina's customers desire terms and conditions that are sufficiently different from Illumina's standard terms and conditions to warrant negotiating a customer-specific supply agreement. (Berry (Illumina) Tr. 841–42.)

Response to Finding No. 985

[redacted]

[redacted]

985.1 In these circumstances, Illumina is very open to negotiating terms and conditions. (Berry (Illumina) Tr. 842.) These negotiations often culminate in a separate supply agreement that captures all of the terms and conditions for that customer that differ from the standard terms and conditions. (Berry (Illumina) Tr. 842.)

Response to Finding No. 985.1

[redacted]

[redacted]

985.2 Illumina enters all of its supply agreements with the intent to follow them and has never entered a supply agreement planning to not follow it. (Berry (Illumina) Tr. 843.)

Response to Finding No. 985.2

[redacted]

[redacted]

[redacted]

[redacted]

986. Customer testimony supports the view that Illumina abides by the terms of its supply agreements. (*See* Fiedler (FMI) Tr. 4471.) For example, Dr. Fiedler, COO of FMI, testified that since entering into a supply agreement with Illumina in 2013:

Response to Finding No. 986

The proposed finding is vague and confusing. The proposed finding is vague because the phrase "supports the view" is ambiguous and undefined. The proposed finding is confusing because it purports to highlight testimony of Mr. Fiedler but fails to actually quote any testimony.

[redacted]

986.1 Illumina has acted in good faith with respect to its obligations under the supply agreement. (Fiedler (FMI) Tr. 4471.)

Response to Finding No. 986.1

The proposed finding is vague because it does not define "good faith" or specify which supply agreement it is referring to.

[redacted]

986.2 FMI is a satisfied customer. (Fiedler (FMI) Tr. 4471.)

Response to Finding No. 986.2

[redacted]

[redacted]

986.3 Illumina has never monkeyed with supply. (Fiedler (FMI) Tr. 4471.)

Response to Finding No. 986.3

This proposed finding is vague and confusing because the term "monkeyed" is ambiguous and undefined.

[redacted]

[redacted]

The proposed finding is against weight of the evidence to the extent it implies that Illumina has never altered a customer's supply. [redacted]

986.4 Illumina has never interrupted supply because it claimed FMI had infringed on Illumina's intellectual property. (Fiedler (FMI) Tr. 4471.)

Response to Finding No. 986.4

The proposed finding is confusing because it is unclear whether it purports to state that

Illumina has never interrupted supply or has never interrupted supply for this specific reason (but may have for other reasons). The proposed finding is vague because it fails to define "interrupt."

[redacted]

986.5 Illumina has never reneged on a commitment it made to FMI. (Fiedler (FMI) Tr. 4471.)

Response to Finding No. 986.5

This proposed finding is confusing because the testimony states only that Illumina has not reneged on a commitment made to Mr. Fiedler. (Fiedler (FMI) Tr. 4471-72.) The proposed finding is vague because it fails to define "reneged."

[redacted]

[redacted]

986.6 Dr. Fiedler trusts Illumina to abide by its commitments. (Fiedler (FMI) Tr. 4471.)

Response to Finding No. 986.6

[redacted]

[redacted]

B. The Development of the Open Offer

987. [redacted]

Response to Finding No. 987

[redacted]

[redacted]

987.1 [redacted]

Response to Finding No. 987.1

[redacted]

987.2 [redacted]

Response to Finding No. 987.2

[redacted]

[redacted]

988. [redacted]

Response to Finding No. 988

[redacted]

[redacted]

[redacted]

988.1 [redacted]

Response to Finding No. 988.1

[redacted]

[redacted]

[redacted]

988.2 [redacted]

Response to Finding No. 988.2

[redacted]

988.3 [redacted]

Response to Finding No. 988.3

[redacted]

[redacted]

988.4 [redacted]

Response to Finding No. 988.4

[redacted]

[redacted]

988.5 [redacted]

Response to Finding No. 988.5

[redacted]

[redacted]

989. [redacted]

Response to Finding No. 989

[redacted]

989.1 [redacted]

Response to Finding No. 989.1

[redacted]

[redacted]

989.2 [redacted]

Response to Finding No. 989.2

[redacted]

[redacted]

989.3 [redacted]

Response to Finding No. 989.3

[redacted]

989.4 [redacted]

Response to Finding No. 989.4

989.5

Response to Finding No. 989.5

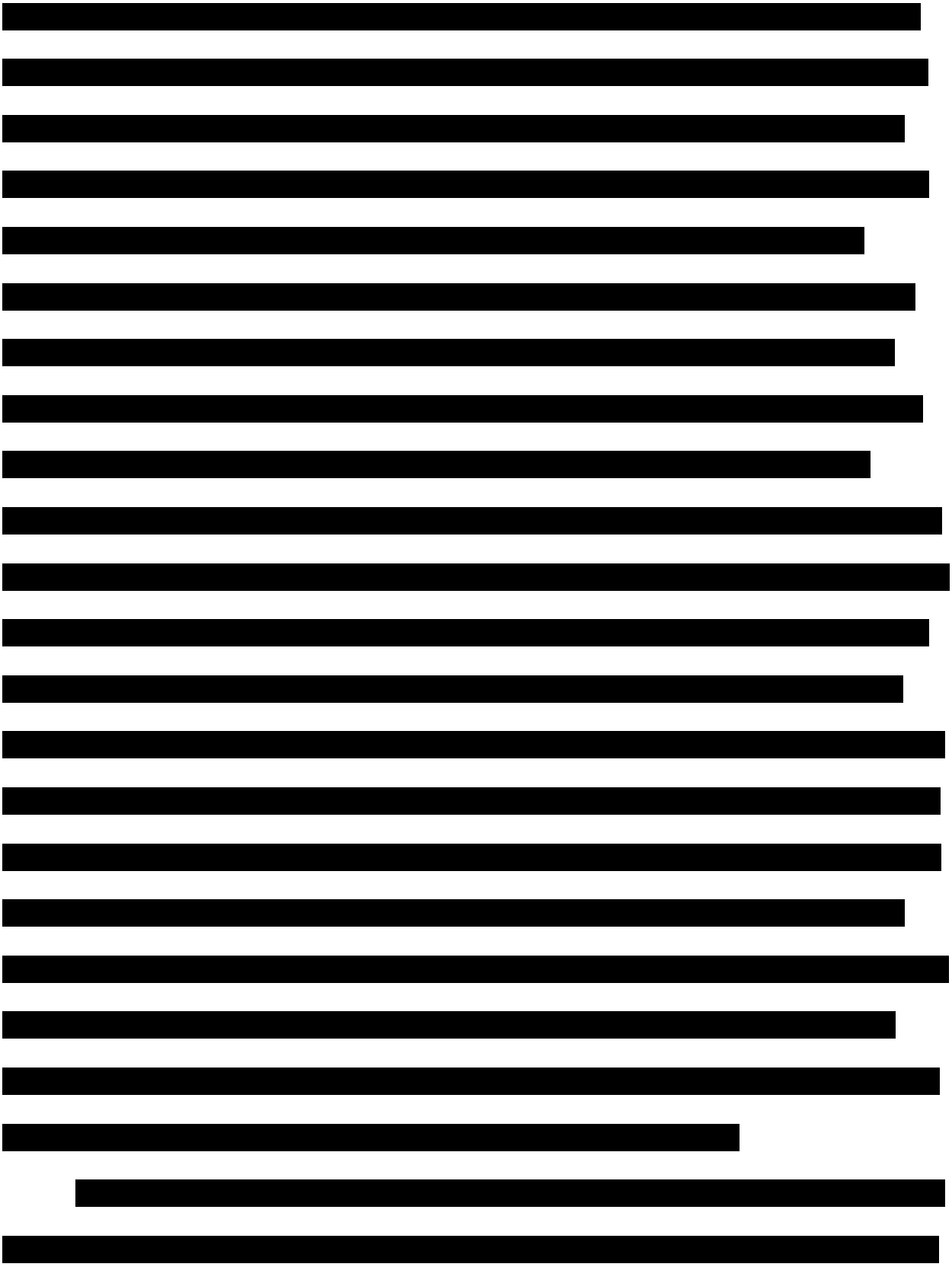
[redacted]

[redacted]

989.6 [redacted]

Response to Finding No. 989.6

[redacted]



[redacted]

989.7 [redacted]

Response to Finding No. 989.7

[redacted]

[redacted]

[redacted]

[redacted]

989.8 [redacted]

Response to Finding No. 989.8

[redacted]

[redacted]

[redacted]

989.9 [redacted]

Response to Finding No. 989.9

[redacted]

[redacted]

989.10 [redacted]

Response to Finding No. 989.10

[redacted]

[redacted]

[redacted]

[redacted]

989.11 [redacted]

Response to Finding No. 989.11

[redacted]

[redacted]

989.12 [redacted]

Response to Finding No. 989.12

[redacted]

[redacted]

[redacted]

989.13 [redacted]

Response to Finding No. 989.13

Complaint Counsel has no specific response to this proposed finding.

989.14 [redacted]

Response to Finding No. 989.14

[redacted]

[redacted]

989.15 [redacted]

Response to Finding No. 989.15

[redacted]

[redacted]

989.16 [redacted]

Response to Finding No. 989.16

[redacted]

[redacted]

989.17

Response to Finding No. 989.17

989.18

Response to Finding No. 989.18

[redacted]

[redacted]

989.19 [redacted]

Response to Finding No. 989.19

[redacted]

[redacted]

989.20 [redacted]

Response to Finding No. 989.20

[redacted]

[redacted]

[redacted]

989.21 [redacted]

Response to Finding No. 989.21

[redacted]

[redacted]

989.22

Response to Finding No. 989.22

[redacted]

989.23 [redacted]

Response to Finding No. 989.23

[redacted]

[redacted]

[redacted]

[redacted]

990. Based on the customer outreach discussions and on what was learned in negotiations with customers [redacted], Illumina developed a standardized supply contract to offer to all of its U.S. oncology customers (the Open Offer.) (Berry (Illumina) Tr. 857, [redacted]

Response to Finding No. 990

[redacted]

[redacted]

991. On March 30, 2021, Illumina made the Open Offer available on its website for all for-profit U.S. oncology customers who purchase NGS products for developing and/or commercializing oncology tests. (deSouza (Illumina) Tr. 2338–39, 2401–02; Berry (Illumina) Tr. 688–89, 709–10; RX4003 (Illumina) at 1; PX0064 (Illumina); PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina).)

Response to Finding No. 991

The proposed finding is inaccurate because Illumina's Open Offer is dated March 29, 2021.

992. While Illumina does not believe that the transaction will have any anticompetitive effect, it made the Open Offer available to address concerns raised by both Complaint Counsel and certain customers that the Illumina-GRAIL transaction would allow Illumina to foreclose GRAIL rivals. (*See* Berry (Illumina) Tr. 688–89, 709–10; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207; PX0064 (Illumina) at 1; PX7122 (Eisenberg (LabCorp) Dep. at 107–08).)

Response to Finding No. 992

[redacted]

Further, this proposed finding is misleading and against the weight of evidence to the extent it purports to represent the views or opinions of Illumina's customers or Complaint Counsel about the Open Offer. The Open Offer does not address customers' or Complaint Counsel's concerns. [redacted]

[redacted]

993. Illumina has made the terms of the Open Offer available to any existing or new customer of Illumina that is a For-Profit Entity and purchases NGS products for developing and/or commercializing oncology tests. (PX0064 (Illumina) at 3.)

Response to Finding No. 993

This proposed finding is misleading to the extent it represents that the Open Offer is sufficient to allay its customers' concerns about the acquisition. [redacted]

[redacted]

[redacted]

993.1 A For-Profit Entity means a for-profit company in the United States that purchases Supplied Products for performing sequencing for liquid biopsy cancer screening or diagnostic tests for clinical oncology purposes, on human samples received from, and delivered to, unaffiliated health care professionals, health care organizations or other laboratories for clinical oncology purposes. (PX0064 (Illumina) at 3.) A For-Profit Entity excludes governments, government agencies, hospitals, research institutes, academic institutions, nonprofits and Illumina Affiliates (including GRAIL.) (PX0064 (Illumina) at 3.)

Response to Finding No. 993.1

Complaint Counsel acknowledges that Respondents' Open Offer letter dated March 29, 2021, includes the quoted language. The proposed finding is misleading to the extent it implies Illumina will abide by the terms of its Open Offer. As [redacted]

[redacted]

993.2 The Supplied Products are "Illumina's NextSeq, NextSeqDx and NovaSeq instruments, and any future sequencing instruments launched by Illumina or its Affiliates, or Sequencing Consumables, that are purchased by Customer for any Customer Use pursuant to the Supply Agreement." (PX0064 (Illumina) at 4–5.)

Response to Finding No. 993.2

[redacted]

[redacted]

993.3 Sequencing Consumables are "those consumables intended by Illumina to be used to perform a sequencing process on Illumina's NextSeq, NextSeqDx and NovaSeq instruments and any future sequencing hardware launched by Illumina or its Affiliates, and includes core consumables that are (i) commercialized or otherwise made available by Illumina to customers or Affiliates of Illumina and (ii) intended by Illumina to be used to perform a sequencing process on any such system. Sequencing Consumables do not include products that were at the 'end of life' or 'end of sale' or were announced (before January 1, 2021) to customers as a planned 'end of life' or 'end of sale'. Sequencing Consumables are limited to products that are shipped to and used in the United States." (PX0064 (Illumina) at 4.)

Response to Finding No. 993.3

[redacted]

[redacted]

993.4 The fact that the Open Offer is available to more than just MCED test developers makes the Open Offer more effective in protecting competition and limiting Illumina's ability to foreclose GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 26–27).) It also makes the Open Offer easier to implement because it applies to a class of customers who are readily identifiable. (RX6002 (Guerin-Calvert Trial Dep. at 27).)

Response to Finding No. 993.4

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Ms. Guerin-Calvert as the only source of evidence supporting this fact in contravention of this Court's Order. This Court should disregard this evidence.

Further, Complaint Counsel restate the objection made at Ms. Guerin-Calvert's trial deposition and move to strike the cited testimony to the extent there's analysis of how other oncology customers may impose a constraint.

This proposed finding is also misleading and unsupported to the extent it purports to speak for the needs or opinions of MCED developers while relying solely on the self-serving testimony of Defendants' paid expert. [redacted]

[redacted]

994. For customers who signed the Open Offer before the close of the acquisition, the terms took effect on August 18, 2021, when the Illumina-GRAIL transaction closed; for others, the terms will take effect immediately upon signing. (PX0064 (Illumina) at 1.)

Response to Finding No. 994

This proposed finding is misleading to the extent it purports to represent what Illumina will do in the future. [redacted]

[redacted]

994.1 The Open Offer is irrevocable, binding and governed by New York law. (PX0064 (Illumina) at 1, 11) ("[t]his irrevocable offer is binding on Illumina.")

Response to Finding No. 994.1

The proposed finding is misleading to the extent it implies Illumina will abide by the terms of its Open Offer. As [redacted]

[redacted]

Ultimately, as [redacted]

994.2 Illumina executives have made several public commitments to the Open Offer, including under oath at this trial, thus giving reasons even beyond New York contract law for Illumina to adhere to the Open Offer. (*See, e.g.*, Berry (Illumina) Tr. 688–89, 709–10; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207.)

Response to Finding No. 994.2

The proposed finding is vague because it does not define or describe which "public commitments" it is referring to.

The proposed finding is misleading to the extent it implies that trial testimony and public statements made by Illumina executives will make Illumina abide by the terms of its Open Offer.

As [redacted]

The proposed finding is misleading to the extent it implies that Illumina cares about its reputation enough that the public statements regarding the Open Offer will make them abide by the terms. The weight of the evidence shows that Illumina's reputation among its customers is already poor. [redacted]

[redacted] Invitae's Mr. Stahl and Singlera's Mr. Gao both testified that Illumina is the 800-pound gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2951; PX7044 (Stahl (Invitae) IHT at 49-50); *see also* Gao (Singlera) Tr. 2947-48). Illumina "dominate[s]" the industry. (PX7044 (Stahl (Invitae) IHT at 49-50)).

Additionally, Illumina cares less about their reputation because customers have nowhere else to go and their actions to foreclose rivals may go undetected. [redacted]

[redacted]

Illumina has acknowledged that its reputation could suffer by closing the transaction in Europe but did it anyway. Illumina disclosed that consummating the transaction when it did could lead to "other adverse consequences to, among other things, its reputation[.]" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

995. Existing or new customers of Illumina may sign the Open Offer at any time until 6 years after the close of Illumina's acquisition of GRAIL, which is August 18, 2027. (Berry (Illumina) Tr. 861–62.) Customers thus do not need to make a rapid decision whether to sign the Open Offer. (Nolan (Freenome) Tr. 2785.)

Response to Finding No. 995

The proposed finding is misleading to the extent it implies that Freenome's CEO, Mr. Nolan testified that Freenome has not signed the Open Offer because simply there is no hurry.

[redacted]

[redacted]

996. On September 8, 2021, Illumina amended the Open Offer to offer additional benefits and protections to customers. (RX3935 (Illumina) at 1; deSouza (Illumina) Tr. at 2405–06.) This addendum provided customers with greater protections in terms of pricing, access to products and services, and enforcement, as outlined below. (RX3935 (Illumina) at 2–3; deSouza (Illumina) Tr. at 2407–09.)

Response to Finding No. 996

The proposed finding is vague because it fails to define or describe what "additional benefits and protections" the amended Open Offer provides to customers. The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza. No other evidence or customer testimony is cited to explain whether these added terms, which were first presented in the middle of trial, are beneficial to customer and provide "protections." Therefore, this Court should disregard the proposed finding.

997. The Open Offer effectively addresses the concerns that FTC has raised that Illumina will have the incentive and ability to anticompetitively disadvantage GRAIL's rivals now that Illumina has re-acquired the remainder of GRAIL that it did not already own. (RX6002 (Guerin-Calvert Trial Dep. at 20–21).)

Response to Finding No. 997

The proposed finding is vague because it fails to define or describe the phrase "effectively address." The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry to support Respondents' proposed "fact."

The proposed finding is an improper legal conclusion which cites to no customer testimony or factual evidence to support its claim. [redacted]

[redacted]. Guardant's Mr. Getty testified, "the [open] offer that is put forward is nothing more than a paper tiger. It's very difficult to understand how that would alleviate our concerns about a combined GRAIL and Illumina organization," adding that "[u]ltimately, . . . we don't have an option." (PX7105 (Getty (Guardant) Dep. at 78-79)). [redacted]

[redacted]

997.1 The Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

Response to Finding No. 997.1

The proposed finding is vague because it fails to define or describe the phrase "economically necessary." The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry to support Respondents' proposed "fact."

Additionally, the proposed finding is misleading to the extent it implies that the Open Offer can account for every situation that may occur over the next 12-years. [redacted] Mr. Getty further testified that he is unaware of all the issues that Guardant may face with Illumina as its supplier over the next 12 years because Guardant is "in a rapidly-evolving space that, you know, has remained stagnant very infrequently. And so ultimately just by virtue of the nature of 12 years on, it's challenging to

see, but even in the sort of short term, it's difficult to even predict what's going to happen next month." (PX7105 (Getty (Guardant) Dep. 82)). Even Illumina's Ms. Berry testified that its "fair to assume" that it's difficult to know every situation that may take place over the course of a 12-year supply agreement because "there's a lot of dynamic things that are happening amongst [Illumina's] customers." (Berry (Illumina) Tr. 694; [redacted])

997.2 The Open Offer addresses the specific concerns about market power and related conduct raised by Complaint Counsel, its expert, Dr. Fiona Scott Morton, and certain Illumina customers. (RX6002 (Guerin-Calvert Trial Dep. at 22).)

Response to Finding No. 997.2

The proposed finding is vague because it fails to define or describe what "specific concerns," "market power," "related conduct," and "certain Illumina customers" Respondents are referring to. The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry or any customer actually subject to the Open Offer's terms to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

997.3 The Open Offer provides a comprehensive set of protections for its customers for all aspects of conduct and competition including access, pricing and quality of products and services, and rights to develop distributable IVD kits on Illumina's FDA-regulated systems. (RX6002 (Guerin-Calvert Trial Dep. at 22, 94–95).)

Response to Finding No. 997.3

The proposed finding is vague because it fails to define or describe what "comprehensive," "all aspects of conduct and competition," "access," and "certain Illumina customers" Respondents are referring to. Nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry or any customer actually subject to the Open Offer's terms to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

997.4 The Open Offer provides for effective monitoring and enforceability mechanisms. (RX6002 (Guerin-Calvert Trial Dep. at 22).)

Response to Finding No. 997.4

The proposed finding is vague because it fails to define or describe what "effective monitoring" and "enforceability mechanisms" mean. The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry or any customer actually subject to the Open Offer's terms to support Respondents' proposed "fact."

The proposed finding is misleading and against the weight of the evidence to the extent it implies that the Open Offer resolves customers concerns about the ability to monitor and enforce the agreement. Guardant's Mr. Getty testified further that "a contract is only as good as it is enforceable. And ultimately, you know, our ability – our ability, being Guardant's ability . . . to investigate adherence to the term of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)). Mr. Getty explained the "nearly impossible" enforcement of a contract with Illumina: "A contract is only as good as it is enforceable. And ultimately, [Guardant's ability] to investigate adherence to the terms of that contract is nearly impossible."

(PX7105 (Getty (Guardant) Dep. at 79-80)).

998. Additionally, extrinsic aspects of the Open Offer will increase its enforceability. (RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

Response to Finding No. 998

The proposed finding is vague because it fails to define or describe what "extrinsic aspects" of the Open Offer is referring to. The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry or any customer actually subject to the Open Offer's terms to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

998.1 All of the provisions of the Open Offer are publicly known and publicly available because the Open Offer is posted on Illumina's website. (deSouza (Illumina) Tr. 2338–39, 2401; RX4003 (Illumina) at 1; PX0064 (Illumina); PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); PX7076 (Berry (Illumina) Dep. at 275–76.)

Response to Finding No. 998.1

The proposed finding is vague because it fails to define what "publicly known" means. Complaint Counsel does not disagree that Illumina's Open Offer is posted on Illumina's website.

The proposed finding is misleading to the extent Respondents are implying that any breach of the Open Offer will also be publicly known. The Open Offer's arbitration provision provides that arbitration proceedings shall be submitted to "confidential binding arbitration to determine final terms and conditions of the supply agreement, or to settle the dispute as to the terms of a supply agreement." (PX0064 at 010 (Illumina Open Offer agreement, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding to the extent it purports to describe what is "publicly known.

> 998.2 The letter accompanying the publicly available Open Offer indicates that the Open Offer's purpose is to allay concerns and constraining conduct that could competitively disadvantage rivals. (PX0064 (Illumina) at 1.)

Response to Finding No. 998.2

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the provision that Illumina is providing the Open Offer "to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in Next Generation Sequencing ("NGS")." (PX0064 at 001 (Illumina Open Offer agreement, Mar. 29, 2021)). However, the proposed finding is misleading to the extent that it implies the Open Offer actually resolves customer concerns. [redacted]

[redacted]

[redacted]

998.3 The Open Offer was made available to a large number of customers—all of Illumina's for-profit clinical oncology customers in the United States. (RX4003 (Illumina's Oncology Contract Terms Website) at 1.)

Response to Finding No. 998.3

This proposed finding is vague, unsupported, and misleading. This proposed finding is vague and unsupported because neither the proposed finding nor the cited document define a "large number" of customers.

This proposed finding is misleading to the extent it represents that the Open Offer is sufficient to allay its customers' concerns about the acquisition. [redacted]

[redacted]

998.4 All of these extrinsic aspects of the Open Offer—its publicness, its strong preamble and its availability to a large number of customers—exert external pressure to make the Open Offer more effective. (RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

Response to Finding No. 998.4

The proposed finding is vague because it fails to define or describe what "extrinsic aspects" of the Open Offer it is referring to. Additionally, it is vague because it fails to define or describe what the terms and phrases "publicness," "strong preamble," and "exert external pressure" mean.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Ms. Guerin-Calvert as the only source of evidence supporting this fact in contravention of this Court's Order. This Court should disregard this evidence.

This proposed finding is also misleading and unsupported to the extent it purports to speak for the needs or opinions of Illumina's customers while relying solely on the self-serving testimony of Defendants' paid expert. [redacted]

[redacted]

998.5 [redacted]

Response to Finding No. 998.5

[redacted]

[redacted]

[redacted]

998.6 [redacted]

Response to Finding No. 988.6

[redacted]

[redacted]

999. The Open Offer also represents an improvement for customers over the premerger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 37, 52–53, 57); *see also* RX6000 (Carlton Trial Dep. at 48).)

Response to Finding No. 999

The proposed finding is vague because it fails to define or describe the term "improvement" and the phrase "premerger status quo."

[redacted]

The proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer have changed. [redacted]

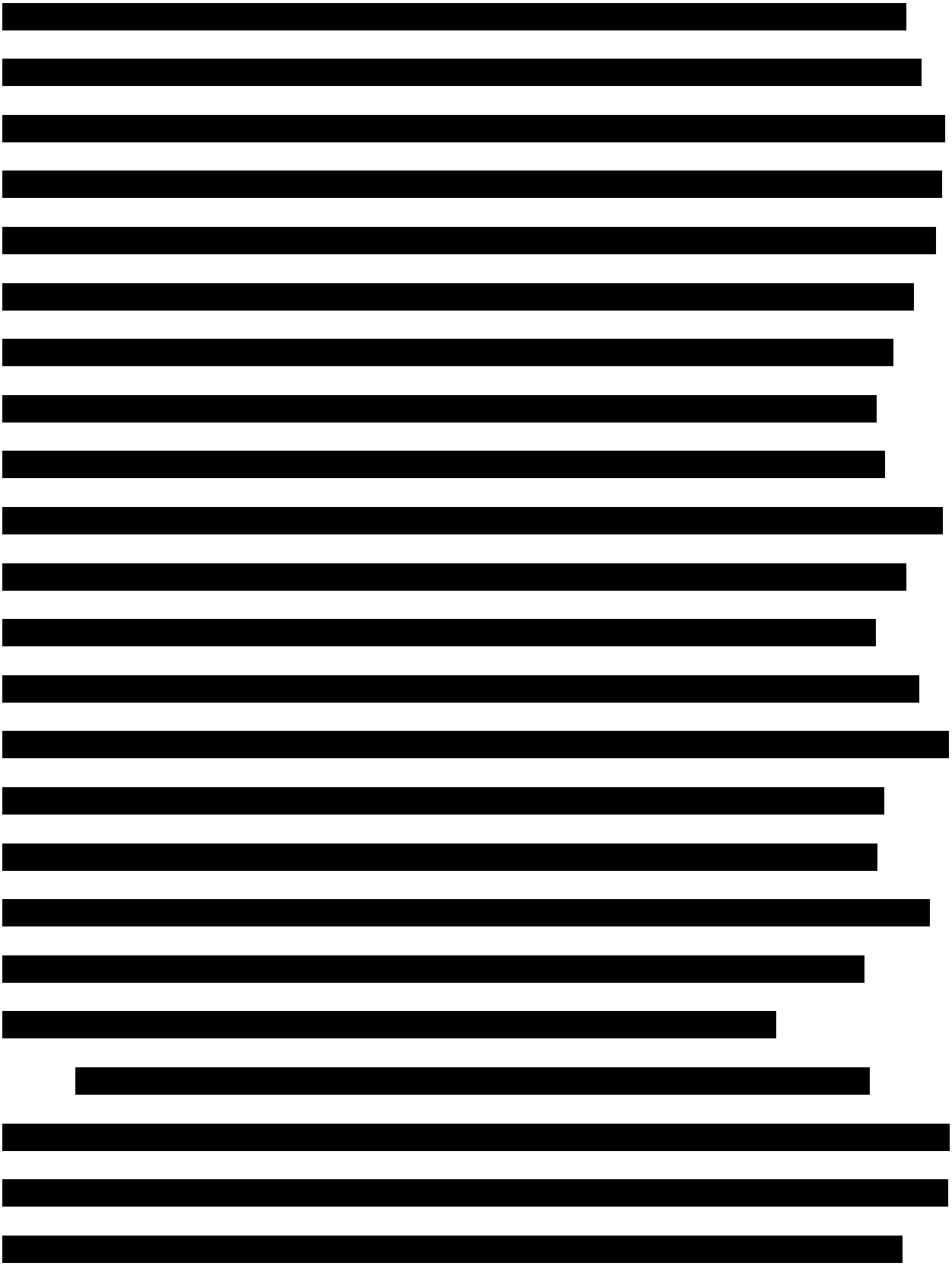
C. Illumina's Binding Commitments in the Open Offer

1. Term, Unilateral Termination, and Purchase Orders

1000. The Open Offer provides for a 12–year supply contract for the Supplied Products. (Berry (Illumina) Tr. 690–91, 861, 874–75; Conroy (Exact/Thrive) Tr. 1725; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 5.)

Response to Finding No. 1000

Complaint Counsel acknowledges that Respondents' Open Offer states that its term is for 12-years. (PX0064 at 005 (Illumina, Open Offer Letter, Mar. 29, 2021)). [redacted]



[redacted]

1000.1 The Open Offer "shall be effective for twelve (12) years from the closing of the Transaction, regardless of the date either party signs this Supply Agreement." (PX0064 (Illumina) at 5.) Therefore, the Open Offer and Addendum are in effect until August 18, 2033 for any customer that signs these agreements. (PX0064 (Illumina) at 5; PX0378 (Illumina) at 3.)

Response to Finding No. 1000.1

Complaint Counsel has no specific response to the finding that the Open Offer has a term of 12 years. The proposed finding is misleading to the extent that it implies Illumina will abide by any signed agreements until August 18, 2033. Mr. Getty testified that "a contract is only as good as it is enforceable. And ultimately, you know, our ability – our ability, being Guardant's ability . . . to investigate adherence to the term of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)). [redacted]

1000.2 The Open Offer's 12–year term is longer than the typical agreements between Illumina and its customers in the pre-merger world, though some customers entered into long-term agreements with Illumina in the past. (Berry (Illumina) Tr. 690–91.) The 12–year term was chosen to assure customers that Illumina was absolutely invested in maintaining longstanding relationships with these customers as a technology provider. (Berry (Illumina) Tr. 862.)

Response to Finding No. 1000.2

The proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer

have changed. [redacted] Guardant's Mr. Getty testified that he does not think a contract between Guardant and Illumina could eliminate Illumina's incentives to favor Grail. (PX7105 (Getty (Guardant) Dep. at 79-80)). [redacted]

The proposed finding is also misleading to the extent it implies the length of the open offer is sufficient to anticipate the changes over the next decade. As [redacted] (CCFF ¶ 4966). [redacted]

[redacted]

Lastly, the proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas and the Open Offer signatory, Nicole Berry. No other evidence is cited explained why a 12-year terms was selected. Therefore, this Court should disregard the proposed finding.

> 1000.3 A 12–year term is consistent with what is normally provided in consent decrees that the FTC and the DOJ have approved historically. (RX6002 (Guerin-Calvert Trial Dep. at 28); *see, e.g.*, RX3082 (*In re Broadcom Ltd.* Decision and Order) at 11; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 4).)

Response to Finding No. 1000.3

The proposed finding is vague because it fails to define what "normally provided" means. Additionally, the proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer have changed. [redacted] Guardant's Mr. Getty testified that he does not think a contract between Guardant and Illumina could eliminate Illumina's incentives to favor Grail. (PX7105 (Getty (Guardant) Dep. at 79-80)). [redacted]

[redacted]

The Commission's decision to accept a remedy or block a transaction is based on the facts in that matter, not the actions taken in a different matter with different facts. The operative question is not what the Commission has done in the past; it is whether the Respondents' Open Offer fully restores the competitive status quo that existed prior to the merger. For all of the reasons Complaint Counsel explained in its Post-Trial brief, Respondents have failed to answer this question. [redacted] Therefore, this Court should disregard the proposed finding.

> 1000.4 The 12–year term is an improvement on the status quo, in which many customers do not have supply agreements and those that do have supply agreements have shorter term agreements. (RX6002 (Guerin-Calvert Trial Dep. at 29); PX7085 (Harada (Exact/Thrive) Dep. at 94).)

Response to Finding No. 1000.4

The proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer have changed. [redacted] Guardant's Mr. Getty testified that he does not think a contract

between Guardant and Illumina could eliminate Illumina's incentives to favor Grail. (PX7105 (Getty (Guardant) Dep. at 79-80)).

1000.5 The 12–year term provides customers with long-term protections and gives customers certainty about price, quality, access and conduct for the next 12 years. (RX6002 (Guerin-Calvert Trial Dep. at 28–29).)

Response to Finding No. 1000.5

The proposed finding is vague because it fails to define "customer[] certainty," "quality," "access," and "conduct." The proposed finding is misleading and against the weight of the evidence. For example,

[redacted]

Even the signatory of the Open Offer admitted to the failures of Illumina's long-term supply agreement. Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71) (testifying that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.")). Ms. Berry testified that Illumina's customers would not know whether they have access to prerelease products at the same time as Grail "unless Illumina proactively communicated such." (Berry (Illumina) Tr. 701). Ms. Berry testified at trial that Section 4(c) of the open offer does not prevent GRAIL from having knowledge of Illumina's new technology before other companies developing oncology tests. (Berry (Illumina) Tr. 708). Under the open offer, Grail can learn the specifications of new Illumina sequencers before its rival MCED test developers. (Berry (Illumina) Tr. 708). Ms. Berry testified that if Illumina does introduce an instrument with a

higher throughput than the NovaSeq, currently Illumina's highest throughput instrument, then the 43 percent price decrease would only apply to that new, higher throughput sequencer. (Berry (Illumina) Tr. 712). Therefore, this Court should disregard the proposed finding.

1000.6 The 12–year term allows customers to plan for the long term more effectively. (Fiedler (FMI) Tr. 4485; RX6002 (Guerin-Calvert Trial Dep. at 28–29).)

Response to Finding No. 1000.6

The proposed finding is against the weight of the evidence to the extent it implies customers can plan for the future of their cancer screening products because of Illumina's long-term supply agreement. [redacted] Further, Ms. Berry testified that its "fair to assume" that it's difficult to know every situation that may take place over the course of a 12-year supply agreement because "there's a lot of dynamic things that are happening amongst [Illumina's] customers." (Berry (Illumina) Tr. 694).

[redacted]

[redacted]

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does cite to any customer with actual knowledge of Illumina's long-term supply agreement to support Respondents' apparent "fact." Ms. Guerin-Calvert made $1,370 per hour for her work on this matter and as of one week prior to her trial deposition, had billed approximately 300 hours on this matter. (RX6002 (Guerin-Calvert Trial Dep. at 110-11)). Therefore, this Court should disregard the proposed finding.

> 1000.7 The 12–year term is long enough to address the foreclosure concerns and alleged competitive harms from the merger. (RX6002 (Guerin-Calvert Trial Dep. at 29–30).)

Response to Finding No. 1000.7

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does cite to any customer with actual knowledge of Illumina's long-term supply agreement to support Respondents' apparent "fact."

This proposed finding is misleading to the extent it implies any customers testified that a 12-year supply agreement is long enough to resolve their concerns regarding the Acquisition.

[redacted]

[redacted]

1001. Under the Open Offer, Customers can terminate the supply relationship with Illumina at any time and without specifying any reason. (Berry (Illumina) Tr. 862–63; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 10.)

Response to Finding No. 1001

The proposed finding is misleading to the extent that it implies the Customer has no prerequisites which must be fulfilled before the Customer can terminate the Illumina supply agreement. Specifically, section 11 of Illumina's March 29, 2021 Open Offer letter states that a customer must provide "ninety (90) days' prior written notice to Illumina" in order to terminate the agreement "without termination liability." (PX0064 at 010 (Illumina Open Offer agreement, Mar. 29, 2021)). No definition for "termination liability" is provided in the Open Offer. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021)).

Additionally, the proposed finding is vague because "Customer" is used as a defined term

but Respondents fail to provide a definition. Therefore, this Court should disregard the proposed finding.

> 1001.1 The Open Offer requires that "Customer has a unilateral right to terminate its supply relationship with Illumina at any time and for any reason without termination liability upon ninety (90) days' prior written notice to Illumina, provided, however, that Customer shall honor all invoices, which invoices shall be issued upon shipment, for Supplied Products ordered under a Purchase Order that was accepted by Illumina prior to the termination date." (PX0064 (Illumina) at 10.)

Response to Finding No. 1001.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. The term "requires," however is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

> 1001.2 The 90–day notice period provision is intended to be as "customer friendly as possible". (Berry (Illumina) Tr. 863.)

Response to Finding No. 1001.2

The proposed finding is vague because it fails to define or explain what as "customer friendly as possible."

The proposed finding is misleading and against the weight of the evidence which shows that Illumina's reputation is already poor. [redacted]

[redacted] Illumina's customers agree. For example, [redacted] Given Illumina's poor reputation, customers must be careful in their dealings with Illumina. As [redacted]

The proposed finding is unsupported because the Open Offer itself makes no mention of the termination provision or any other provision of the agreement being "customer friendly." As Ms. Berry testified the customer has to rely on the "spirt" of the contract as there is no such protection written into the terms of the agreement. (PX7076 (Berry (Illumina) Dep. at 297 (Q. So

from your understanding, a customer's suspicion that Illumina is violating the open offer would arise to the level of a good faith basis? A. I believe that's the spirit with which this 12(a) is written. Q. And how would customers be aware of the spirit? A. I'm not sure that there's a basis for them to be aware of the spirit.")).

Lastly, the proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas and the Open Offer signatory, Nicole Berry. No other evidence is cited to explain how the termination clause is "customer friendly." Therefore, this Court should disregard the proposed finding.

1002. The Open Offer requires that "Illumina cannot terminate this Supply Agreement for convenience during the Term." (PX0064 (Illumina) at 10; *see also* (Berry (Illumina) Tr. 863; deSouza (Illumina) Tr. 2402.)

Response to Finding No. 1002

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. The term "for convenience," however is vague because it is not defined in the Open Offer. It is unclear and uncertain whether Illumina could terminate the Supply Agreement for a purpose that does not meet this "convenience" requirement. As [redacted]

[redacted]

1002.1 This asymmetry in the termination provisions addresses the alleged anticompetitive effects and foreclosure concerns related to the merger: Because Illumina cannot exit the agreement, its conduct will be restrained over the entire 12–year term, but the customer enjoys the benefit of being able to switch to alternative suppliers for sequencing instruments or consumables at any time. (RX6002 (Guerin-Calvert Trial Dep. at 30–31).)

Response to Finding No. 1002.1

The proposed finding is misleading to the extent it implies there is a "asymmetry in the termination provisions" included in the Open Offer and that Illumina cannot exit the agreement. The language of the termination provision included in the open offer uses several terms which are undefined by Respondents and leave loopholes for Illumina to exit the agreement and mess with customers. For example, Respondents provide no definition for "termination liability," "for convenience," and "materially breaches." (PX0064 at 010 (Illumina, Open Offer Letter, Mar. 29, 2021)). The term "for convenience," is vague because it is not defined in the Open Offer. It is unclear and uncertain whether Illumina could terminate the Supply Agreement for a purpose that does not meet this "convenience" requirement.

The proposed finding is misleading and against the weight of the evidence to the extent it implies that MCED customers have an "alternative supplier[]" to switch to. [redacted]

[redacted] Singlera's Dr. Gao described Singlera's relationship with Illumina as like being a "prisoner of war." (PX7042 (Gao (Singlera) IHT at 88)). Dr. Chahine testified that Helio has "looked at different providers. I don't want to say technically we couldn't, but the truth is that the entire category uses Illumina. We're very familiar with Illumina. … The cost is much lower. … [T]here are just a number of … technical advantages and just performance." (PX7077 (Chahine (Helio) Dep. at 26)).

Lastly, the proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does cite to any customer with actual experience in the industry to support Respondents' apparent "fact." Therefore, this Court should disregard the proposed finding.

1003. The Open Offer is "not contingent on any purchase commitments by Customer, nor does it affect Customer's existing unilateral right to terminate its supply relationship with Illumina at any time and for any reason." (PX0064 (Illumina) at 9; *see also* Berry (Illumina) Tr. 864–65.)

Response to Finding No. 1003

Complaint Counsel acknowledges that the quoted language is included in Illumina's open offer agreement published on March 29, 2021. The proposed finding is misleading to the extent it implies that a customer has no prerequisites to termination of the agreement. Respondents acknowledge in their own finding 1001.1 that the customers must provide "ninety (90) days' prior written notice to Illumina" in order to avoid "termination liability." Termination liability is an undefined term. (PX0064 at 010 (Illumina Open Offer agreement, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding.

> 1003.1 The Offer also requires that "[w]ritten purchase orders ("Purchase Orders") submitted in accordance with this Supply Agreement, Illumina's Terms and Conditions, or an operative supply agreement may be rejected by Illumina only if Illumina does not have sufficient supply of the applicable Supplied Product to fulfill the order or if the Purchase Order is not in accordance with standard lead times for the applicable Supplied Product." (PX0064 (Illumina) at 9.)

Response to Finding No. 1003.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. The term "sufficient supply," however is vague because it is not defined in the Open Offer. It is unclear and uncertain what constitutes sufficient supply and leaves loopholes for Illumina to mess with customers supply. [redacted]

Moreover, the proposed finding is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

2. **Uninterrupted and Timely Access to Services**

1004. Under the Open Offer, Illumina must provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

Response to Finding No. 1004

[redacted]

[redacted]

[redacted]

[redacted]

1004.1 The Open Offer requires that "Customer shall have access to the same product services and support services for purchase relating to the Supplied Products to which GRAIL or any For-Profit Entity has access, or which Customer had access before the Transaction." (PX0064 (Illumina) at 6.)

Response to Finding No. 1004.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. The term "requires," however is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

Additionally, the proposed finding is vague as the Open Offer does not define "product services" or "support services." (PX0064 § 4.a. (Illumina, Open Offer Letter, Mar. 29, 2021)). The Open Offer does not explain how such services could be measured to ensure consistency in treatment between Grail and its rivals. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

The proposed finding is misleading to the extent it implies customers will be able to know what services Illumina is providing to Grail and other Illumina customers. [redacted])). Mr. George, Invitae's CEO, testified that under Open Offer term 4(a) it is "not clear" how Invitae will know they are receiving access to the same product services and support services as GRAIL. (PX7081 (George (Invitae) Dep. at 93-94)).

Even Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71) (testifying that Illumina could "say simple things like 'We can't get a technician out to your

sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.")) Additionally, Respondents' own expert, Ms. Guerin-Calvert, agreed that an Illumina customer is not well positioned to compare the services it receives from Illumina with the services that its competitor receives. (RX6002 (Guerin-Calvert Trial Dep. at 152); *see also* CCFF ¶¶ 4508-09). Therefore, this Court should disregard the proposed finding.

> 1004.2 The Open Offer also requires that "[f]or such services, Customer shall have access to the same volume-based pricing that GRAIL has access to for the equivalent level of service, or to which Customer had access before the transaction, at the Customer's option." (RX3935 (Illumina) at 2.)

Response to Finding No. 1004.2

Complaint Counsel acknowledges that Respondents' Amended Open Offer letter dated September 8, 2021 includes the quoted language. Respondents' revised the terms of its Open Offer letter during the middle of trial. Moreover, the term "requires," is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted].

The proposed finding is vague because the terms "access," "equivalent level," and "service" are not defined. Nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). The Open Offer does not explain how such services could be measured to ensure consistency in treatment between Grail and its rivals. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

The proposed finding is misleading to the extent it implies customers will be able to know what services and at what price Illumina is providing to Grail and other Illumina customers. [redacted]). Mr. George, Invitae's CEO, testified that under Open Offer term 4(a) it is "not clear" how Invitae will know they are receiving access to the same product services and support services as GRAIL. (PX7081 (George (Invitae) Dep. at 93-94)).

Even Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71)

(testifying that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.")). Additionally, Respondents' own expert, Ms. Guerin-Calvert, agreed that an Illumina customer is not well positioned to compare the services it receives from Illumina with the services that its competitor receives. (RX6002 (Guerin-Calvert Trial Dep. at 152); *see also* CCFF ¶¶ 4508-09). Therefore, this Court should disregard the proposed finding.

> 1004.3 Illumina customers can purchase 3 different levels of service contracts—gold, silver or bronze. (Berry (Illumina) Tr. 681–82.) The different levels of service contracts vary based on considerations like response times and the number of instances that Illumina technicians will proactively service the customer's instruments. (Berry (Illumina) Tr. 682.)

Response to Finding No. 1004.3

Complaint Counsel acknowledges that customers have different levels of service contracts with Illumina. However, the proposed finding is misleading and incomplete to the extent it implies Illumina only has three levels of services contracts – gold, silver, or bronze.

[redacted]

> 1004.4 To comply with the access-to-services provision and ensure consistency in treatment, Illumina keeps track of services that customers order using service contract SKUs. (Berry (Illumina) Tr. 866–68.) When a customer purchases a service SKU, there is an agreement that describes aspects of the service relationship such as turnaround time and the number of preventative maintenances to which a customer is entitled. (Berry (Illumina) Tr. 867.) As with products, there is a standard list of orderable service SKUs, each associated with a standard U.S. list price. (Berry (Illumina) Tr. 868–69.)

Response to Finding No. 1004.4

The proposed finding is vague because "access-to-services provision" is undefined, and it is unclear what provision this is referring to. The proposed finding is also vague because "consistency in treatment" is undefined and unclear. It is unclear how similar a customer's "treatment" needs to be to qualify as being consistent.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. No customer testimony, documents, or written policies and procedures support Respondents' proposed "fact."

[redacted]

> 1004.5 Illumina has a long and sophisticated onboarding process when it hires new service technicians, which helps ensure that service quality among technicians is consistent. (Berry (Illumina) Tr. 869–70.) It also ensures consistent service among technicians by tracking individual cases to determine whether there is any gap in performance between service engineers. (Berry (Illumina) Tr. 870–71.)

Response to Finding No. 1004.5

The proposed finding is vague because it fails to define or describe Illumina's "long and sophisticated onboarding process." The proposed finding is vague because it fails to describe

how Illumina's "onboarding process" "helps ensure that service quality among technicians is consistent."

The proposed finding is vague because it fails to define or describe what "consistent" means. The proposed finding is also misleading to the extent that it implies "consistent" means identical. [redacted]

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. No documents or written policies and procedures support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

> 1004.6 In order to ensure that it satisfies its obligations when a customer orders a service SKU, Illumina measures its customer support using key performance indicators (KPIs). (Berry (Illumina) Tr. 867–68.) These KPIs include metrics like instrument downtime or the length of time between when a case is opened to when it is closed. (Berry (Illumina) Tr. 867–68.) These KPIs enable Illumina to compare how it performs in terms of service and support across individual customers or groups of customers. (Berry (Illumina) Tr. 868.)

Response to Finding No. 1004.6

The proposed finding is vague because it fails to describe the various "key performance indicators (KPI)" that Illumina uses.

[redacted]

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. No documents or written policies and procedures support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

> 1004.7 If Illumina delayed or refused to service an instrument that belonged to a customer who had signed the Open Offer, Illumina would be in breach of the agreement. (Berry (Illumina) Tr. 871.) Illumina would also be in breach if it provided worse services to a customer laboratory who did not also purchase Galleri. (Berry (Illumina) Tr. 879.) Moreover, refusing to service instruments would hurt Illumina's overall business because customers would stop buying kits from Illumina. (Berry (Illumina) Tr. 871–72.)

Response to Finding No. 1004.7

The proposed finding is misleading to the extent it implies that Illumina customers will know whether Illumina breaches the Open Offer by delaying or refusing to provide service and that Illumina customers know what services are being provided to other Illumina customers. First, the Open Offer does not define "product services" or "support services." (PX0064 § 4.a. (Illumina, Open Offer Letter, Mar. 29, 2021)). Second, The Open Offer does not explain how such services could be measured to ensure consistency in treatment between Grail and its rivals. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). [redacted]

[redacted]

[redacted]

[redacted]

Lastly, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

1004.8 The Open Offer's equal services commitment places customers who have never had a supply agreement and who purchase subject to a purchase order in a superior

position to the pre-merger status quo by removing the uncertainty of accessing Illumina's servicing resources. (RX6002 (Guerin-Calvert Trial Dep. at 57).)

Response to Finding No. 1004.8

[redacted]

1004.9 The equal services commitment ensures that customers will receive at least the same level of service that they did before the merger. (RX6002 (Guerin-Calvert Trial Dep. at 58).)

Response to Finding No. 1004.9

This Court held that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This Court should disregard this evidence.

[redacted]

[redacted]

1004.10 The commitment also addresses the concern that customers could suffer a delay in support services because the commitment requires that customers receive the same quality and type of services. (RX6002 (Guerin-Calvert Trial Dep. at 58–59).)

Response to Finding No. 1004.10

This Court held that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This Court should disregard this evidence.

Moreover, the proposed finding is misleading to the extent it implies customers know the quality and type of services received by other Illumina customers. [redacted]

[redacted])). Mr. George, Invitae's CEO, testified that under Open Offer term 4(a) it is "not clear" how Invitae will know they are receiving access to the same product services and support services as GRAIL. (PX7081 (George (Invitae) Dep. at 93-94)).

Even Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71) (testifying that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.")). Additionally, Respondents' own expert, Ms. Guerin-Calvert, agreed that an Illumina customer is not well positioned to compare the services it receives from Illumina with the services that its competitor receives. (RX6002 (Guerin-Calvert Trial Dep. at 152); *see also* CCFF ¶¶ 4508-09).

The proposed finding is misleading to the extent it implies customers can account for service delays. For example, Guardant's testified that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that

could create challenges around turnaround time and disappoint customers and therefore hurt us competitively." (PX7105 (Getty (Guardant) Dep. at 69-71)). Therefore, this Court should disregard the proposed finding.

3. Uninterrupted and Timely Access to the Latest Sequencing Instruments and Core Consumables

1005. The Open Offer provides customers the same access to purchase sequencing instruments and core consumables to which GRAIL has access. (Rabinowitz (Natera) Tr. 421; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

Response to Finding No. 1005

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

1005.1 The Open Offer requires that "Customer shall have access to the Supplied Products for purchase that GRAIL . . . has access, within 5 days of when GRAIL . . . is offered such access (if not earlier) for purchase." (RX3935 (Illumina) at 2.)

Response to Finding No. 1005.1

Complaint Counsel acknowledges that Respondents' Additional Supply Agreement Terms to the Open Offer, which was presented for the first time in the middle of trial, includes

the quoted language. The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

1005.2 For example, if Illumina created a "NovaSeq-3", there is no way that it could provide it to GRAIL (meaningfully) ahead of potential competitors because

everyone would receive access to it within 5 days of GRAIL receiving access. (deSouza (Illumina) Tr. 2448.)

Response to Finding No. 1005.2

The proposed finding is vague because it fails to define or describe what the caveat "meaningfully" means.

[redacted]

1005.3 Illumina will ensure that GRAIL does not get access to a sequencing instrument or core consumable before other customers get access because Illumina is designing its organization to prevent leaks between Illumina and GRAIL. (Berry (Illumina) Tr. 878.)

Response to Finding No. 1005.3

This proposed finding is unsupported, vague, and misleading. Ms. Berry testified that it was "her understanding" that Illumina was "designing . . . [the] organization to prevent such leaks," Berry (Illumina) Tr. 878.), but did not and could not predict what Illumina will do or

"ensure" in the future. Further, the phrase "designing its organization" is vague and undefined. The proposed finding is also unsupported to the extent it attempts to speak to the concerns of Illumina's customers while relying solely on the speculative and self-serving testimony of an Illumina executive.

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is misleading to the extent it implies that Illumina can design its organization to prevent leaks between Illumina and GRAIL. [redacted]

[redacted]

The proposed finding is also misleading to the extent it implies that customers will be able to effectively enforce a breach of the Open Offer. If customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (PX0064 at 008 (Illumina Open Offer Agreement, March 29, 2021)). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

Additionally, Illumina does not care much about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted]

[redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

> 1005.4 Further, customers can ensure that Illumina adheres to this provision because the Open Offer requires Illumina to publish and update information about the products and services GRAIL purchases, as well as the pricing grids used for those purchases. (RX3935 (Illumina) at 2.)

Response to Finding No. 1005.4

The proposed finding is misleading to the extent it implies that customers can "ensure that Illumina adheres" to the "Access to Supplied Products" term because the Open Offer "requires" Illumina to publish and update information about the products and services GRAIL

purchases, as well as the pricing grids. The provision in Respondents amended Open Offer terms they are referring to here is the "Grail Purchases and Services" term. This term provides that "Illumina shall publish, on the 'Oncology Contract Terms' website, (i) the Supplied Products, by SKU, that Grail is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing…." RX3935 at 002-003 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). It is unclear from this term whether the product SKU number will tell customer what products Grail is specifically receiving from Illumina. Thus, proposed finding is misleading to the extent it implies that customers can know from the "Oncology Contract Terms" website what products Grail receives from Illumina.

The term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in

the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

This proposed finding is misleading to the extent it implies that Illumina's customers have leverage over Illumina's actions. Illumina customers testified to their minimal negotiating leverage with Illumina, as Illumina is their sole supplier of sequencing instruments, reagents, and service. For example, Singlera's Dr. Gao testified that Singlera has little to no negotiating leverage with Illumina. (PX7042 (Gao (Singlera) IHT at 84-85). Additionally, Dr. Gao testified that in negotiations with Illumina, "their [Illumina's] way is my way or the highway. If you gave [Illumina] that profit margin, well, [Illumina] -- you know, [Illumina] can allow you to survive. If not, you just die." (CCFF ¶ 2719).

The proposed finding is also misleading to the extent it implies that Illumina's breach of the Open Offer would harm Illumina's reputation. If customers are able to discover a potential

breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit the matter to "confidential binding arbitration." (PX0064 at 008 (Illumina Open Offer Agreement, March 29, 2021)). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

In addition, the weight of the evidence shows that Illumina's reputation among its customers is already poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

[redacted]

Additionally, Illumina does not care much about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

1005.5 The Open Offer specifically requires that "Illumina shall publish, on the "Oncology Contract Terms" website, (i) the Supplied Products, by SKU, that GRAIL is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing; and (iii) the pricing grid for both products and services under which GRAIL is purchasing Supplied Products

> and services. To the extent necessary, Illumina shall update this website within 5 days of entry of any purchase order for Supplied Products or any service contract relating to the Supplied Products by GRAIL." (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).)

Response to Finding No. 1005.5

The proposed finding is misleading to the extent it implies that customers can know from the "Oncology Contract Terms" website what products and services Grail receives from Illumina The Open Offer's amended terms, which were presented in the middle of trial, state that "Illumina shall publish, on the 'Oncology Contract Terms' website, (i) the Supplied Products, by SKU, that Grail is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing…." RX3935 at 002-003 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). It is unclear from this term whether the product and service SKU number will tell customer what products and services Grail is specifically receiving from Illumina. Thus, proposed finding is misleading to the extent it implies that customers can know from the "Oncology Contract Terms" website what products Grail receives from Illumina. Even Illumina's executive and Open Offer signatory, Ms. Berry testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)). Certain information, such as a customer's order information and service reports, is confidential and one customer would not have access to another customer's information). (PX7076 (Berry (Illumina) Dep. at 81; 291)). Ms. Berry testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)).

The term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

This proposed finding is misleading to the extent it implies that Illumina's customers have leverage over Illumina's actions. Illumina customers testified to their minimal negotiating leverage with Illumina, as Illumina is their sole supplier of sequencing instruments, reagents, and service. For example, Singlera's Dr. Gao testified that Singlera has little to no negotiating leverage with Illumina. (PX7042 (Gao (Singlera) IHT at 84-85). [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1006. In addition to requiring equivalent access to products for purchase, the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (RX3935 (Illumina) at 2.)

Response to Finding No. 1006

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

[redacted]

[redacted]

1006.1 Specifically, the Open Offer requires that "Customer shall have access to the same information about final product specifications of any new Supplied Product, any new version of a Supplied Product or any Pre-Release Sequencing Product within 5 days of when GRAIL is provided such information." (RX3935 (Illumina) at 2.)

Response to Finding No. 1006.1

The proposed finding is vague because it does not define or describe what "access"

means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

1007. The Open Offer also provides customers the same access to purchase sequencing instruments and core consumables to which any For-Profit Entity has access. (Rabinowitz (Natera) Tr. 421; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

Response to Finding No. 1007

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

1007.1 The Open Offer requires that "Customer shall have access to the Supplied Products for purchase that . . . any For-Profit Entity has access, within 5 days of when . . . such For-Profit Entity . . . is offered such access (if not earlier) for purchase." (RX3935 (Illumina) at 2.)

Response to Finding No. 1007.1

Complaint Counsel acknowledges that Respondents' Additional Supply Agreement Terms to the Open Offer, which was presented for the first time in the middle of trial, includes the quoted language. The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-

002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021))

[redacted]

The proposed finding relies solely upon the self-serving evidence of Illumina's own supply agreement terms and does not cite to any customer with actual experience in the industry and actually subject to the Open Offer's terms to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

[redacted]

[redacted]

1007.2 For example, if Illumina made improvements to a sequencing instrument (such as to its speed, throughput, or cost), there is no way for Illumina to limit these improvements to one particular user or customer. (deSouza (Illumina) Tr. 2446–47.)

Response to Finding No. 1007.2

The proposed finding is misleading to the extent it implies Illumina cannot give Grail early access to new products or inform Grail of its product pipeline. [redacted]

[redacted]

The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza, and does not cite to any customer with actual experience in the industry and actually subject to the Open Offer's terms to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

> 1007.3 Illumina can ensure that it complies with this provision because when Illumina launches a product, the product is made available to all customers at once. (Berry (Illumina) Tr. 877.) In other words, there is no selective restriction that Illumina can apply to a product in a full commercial launch. (Berry (Illumina) Tr. 877.)

Response to Finding No. 1007.3

This proposed finding is speculative and misleading. This proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Illumina VP and General Manager, Americas, Nicole Berry, that is uncorroborated by any ordinary course documents or customer testimony. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Ms. Berry's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading to the extent it equates a product launch with actual availability of the product to certain customers at a certain time, and to the extent it implies that a "selective restriction" is the only way that Illumina could evade the provision in question. Further, the phrase "selective restriction" is vague and undefined.

The proposed finding is misleading to the extent it implies that Illumina customers will

know what other customers are purchasing. Even Illumina's executive and Open Offer signatory, Ms. Berry testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)). Certain information, such as a customer's order information and service reports, is confidential and one customer would not have access to another customer's information). (PX7076 (Berry (Illumina) Dep. at 81; 291)). Ms. Berry testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)).

The proposed finding is also misleading because it omits Ms. Berry's testimony—on the very same page of the trial transcript—stating that Illumina *does* give some customers access to certain products prior to launch. (Berry (Illumina) Tr. 877 ("for certain products we . . . [make] these pre-release sequencing products accessible to limited numbers of customers prior to launch for the purposes primarily of that customer providing us with feedback.")). Therefore, this Court should disregard the proposed finding.

> 1007.4 Also, the Open Offer contains a table showing the specific orderable SKUs that comprise the Supplied Products under the Open Offer. (Berry (Illumina) Tr. 878; PX0064 (Illumina) at 15–27.) If Illumina launched a new product, it would update this table accordingly. (Berry (Illumina) Tr. 878.)

Response to Finding No. 1007.4

This proposed finding is vague, unsupported, and misleading to the extent it implies that all customers will have access to the same information at the same time, but neither the proposed finding nor the cited sources support that or provide any timing for updating the table, nor do the cited sources indicate any requirement for providing the updated table to all customers on the same timeframe. Additionally, it is unclear whether a new product SKU number will tell customer whether Illumina has launched a new product.

This proposed finding is also inherently speculative. To support the statement that the table will be updated, Respondents cite only to the unfounded, self-serving testimony of Illumina VP and General Manager, Americas, Nicole Berry, uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Ms. Berry's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is also misleading because it omits Ms. Berry's testimony stating that Illumina *does* give some customers access to certain products prior to launch. (Berry (Illumina) Tr. 877 ("for certain products we . . . [make] these pre-release sequencing products accessible to limited numbers of customers prior to launch for the purposes primarily of that customer providing us with feedback.")). Therefore, this Court should disregard the proposed finding.

1008. Customers who sign the Open Offer must also receive equitable access to purchase any Pre-Release Sequencing Products. (Rabinowitz (Natera) Tr. 421; Berry (Illumina) Tr. 702; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

Response to Finding No. 1008

The proposed finding is vague because it fails to define or describe what "equitable access" means. The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

[redacted]

1008.1 The Open Offer requires that "Customer shall have access for purchase to any Pre-Release Sequencing Product to which GRAIL or any For-Profit Entity is offered access within 5 days of when GRAIL or such For-Profit Entity, as applicable, is offered

such access (if not earlier), and for the same categories of uses . . . ." (PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

Response to Finding No. 1008.1

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). The proposed finding is vague because it fails to define or describe what "for the same categories of uses" means.

[redacted]

[redacted]

[redacted]

1008.2 Pre-Release Sequencing Product "means Illumina sequencing hardware or Sequencing Consumables that are not available for purchase in Illumina's product catalogue. Such sequencing hardware or Sequencing Consumables shall include any re-designed or modified products made available to any For- Profit Entity or to GRAIL that optimize, in any material respect, a product's interoperability, capabilities, or performance." (PX0064 (Illumina) at 4.)

Response to Finding No. 1008.2

Complaint Counsel acknowledges that Illumina's Open Offer dated March 29, 2021 includes this definition.

1008.3 The pre-release access provision was intended to assure customers that there would be no advantage conferred on GRAIL or another commercial player in the oncology testing space. (Berry (Illumina) Tr. 880.)

Response to Finding No. 1008.3

This proposed finding is vague because the term "advantage" is undefined.

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

This proposed finding is also inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Illumina VP and General Manager, Americas, Nicole Berry. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Ms. Berry's base conjecture, this proposed finding of fact should be disregarded.

To the extent the cited testimony references a provision of the Open Offer, as [redacted]

[redacted]

[redacted]

1008.4 Because providing Pre-Release Sequencing Products to customers is quite unusual, it will be very manageable for Illumina to ensure that it complies with this provision. (Berry (Illumina) Tr. 880.)

Response to Finding No. 1008.4

This proposed finding is vague, speculative, and misleading. It is vague because "quite unusual" is unclear and undefined.

This proposed finding is also inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Illumina VP and General Manager, Americas, Nicole Berry. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Ms. Berry's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading to the extent it implies that Illumina has not provided "pre-released sequencing products to customers" in the past. The Open Offer provides a pre-release sequencing product "means Illumina sequencing hardware or Sequencing Consumables that are not available for purchase in Illumina's product catalogue." (PX0064 at 004 (Illumina,

Open Offer Letter, Mar. 29, 2021)).

The proposed finding is misleading to the extent it implies that Illumina has not provided "pre-released sequencing products to customers" in the past. The Open Offer provides a pre-release sequencing product "means Illumina sequencing hardware or Sequencing Consumables that are not available for purchase in Illumina's product catalogue." (PX0064 at 004 (Illumina, Open Offer Letter, Mar. 29, 2021)).

[redacted]

To the extent the cited testimony references a provision of the Open Offer, as [redacted]

1008.5 Illumina will provide access to Pre-Release Sequencing Products as quickly as practically possible. (Berry (Illumina) Tr. 703–06.)

Response to Finding No. 1008.5

This proposed finding is vague, speculative, and misleading. The phrase "as quickly as practicable" is vague and undefined. The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021))

The proposed finding is misleading to the extent it implies that the Open Offer's terms state that "Illumina will provide access to Pre-Release Sequencing Products as quickly as practically possible." Nowhere in the Open Offer or its amended terms, which were presented in the middle of trial, does Illumina make this commitment. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); RX3935 at (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). This proposed finding is also inherently speculative. Respondents imply that Illumina will treat all customers equally but cite only to the unfounded, self-serving testimony of Illumina VP and General Manager, Americas, Nicole Berry. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Ms. Berry's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is also misleading to the extent it implies that Illumina will do what is best for all its customers. The weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted]

[redacted]

Additionally, Illumina does not care much about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore, this Court should disregard the proposed finding.

1008.6 Considering the length of time that it takes to develop a test on a sequencing platform, 5 days is "a very inconsequential amount of time" for a developer making a test. (*see* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted] PX7100 (Chudova (Guardant) Dep. at 75–79); [redacted]

Response to Finding No. 1008.6

The proposed finding is misleading and incorrect to the extent it implies that customer have stated that 5 days is an inconsequential amount of time. Illumina's "5-day" time frame was not introduced until September 2021, during the middle of trial, when the customer testimony Respondents cite to here occurred well before September 2021. Respondents do not cite any MCED customer testimony from September 2021.

Respondents incorrectly cite to Illumina's Mr. Aravanis's testimony. Mr. Aravanis testified to Illumina's 45-day notice time frame, not the 5-day notice time frame. (*See* Aravanis (Illumina) Tr. 1930). Mr. Aravanis testified "these tests are developed over many years. Forty-five days is a very inconsequential amount of time relative to the years it takes to develop one of these products." (Aravanis (Illumina) Tr. 1930). Similarly, Respondents incorrectly cite to Illumina's Ms. Berry's testimony. Ms. Berry testified to Illumina's 45-day notice time frame, not the 5-day notice time frame. (*See* Berry (Illumina) Tr. 702-03).

[redacted]

[redacted]

1009. These provisions requiring equitable access to Supplied Products and Pre-Release Sequencing Products very directly address the foreclosure concerns that have been raised. (RX6002 (Guerin-Calvert Trial Dep. at 59–60).)

Response to Finding No. 1009

The proposed finding is vague because it fails to define or describe what "equitable access" means. The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

[redacted]

1009.1 The provisions directly address the concern that products could be withheld so as to disadvantage GRAIL rivals because they require providing equivalent access within a very short time frame. (RX6002 (Guerin-Calvert Trial Dep. at 60).)

Response to Finding No. 1009.1

The proposed finding is vague because it fails to define or describe what "equivalent access" and "very short time frame" mean. The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

1009.2 The provisions directly guarantee that MCED test developers will have notice of technical enhancements and technical upgrades because they require upgraded technologies to be made available to customers on a timely basis. (RX6002 (Guerin-Calvert Trial Dep. at 60–61).)

Response to Finding No. 1009.2

The proposed finding is vague because it fails to define or describe what "directly guarantee," "technical enhancements," "technical upgrades," and "timely basis" mean. The proposed finding is vague because it fails to define or describe how Illumina's Open Offer provisions "directly guarantee that MCED test developers will have notice of technical enhancements…"

[redacted]

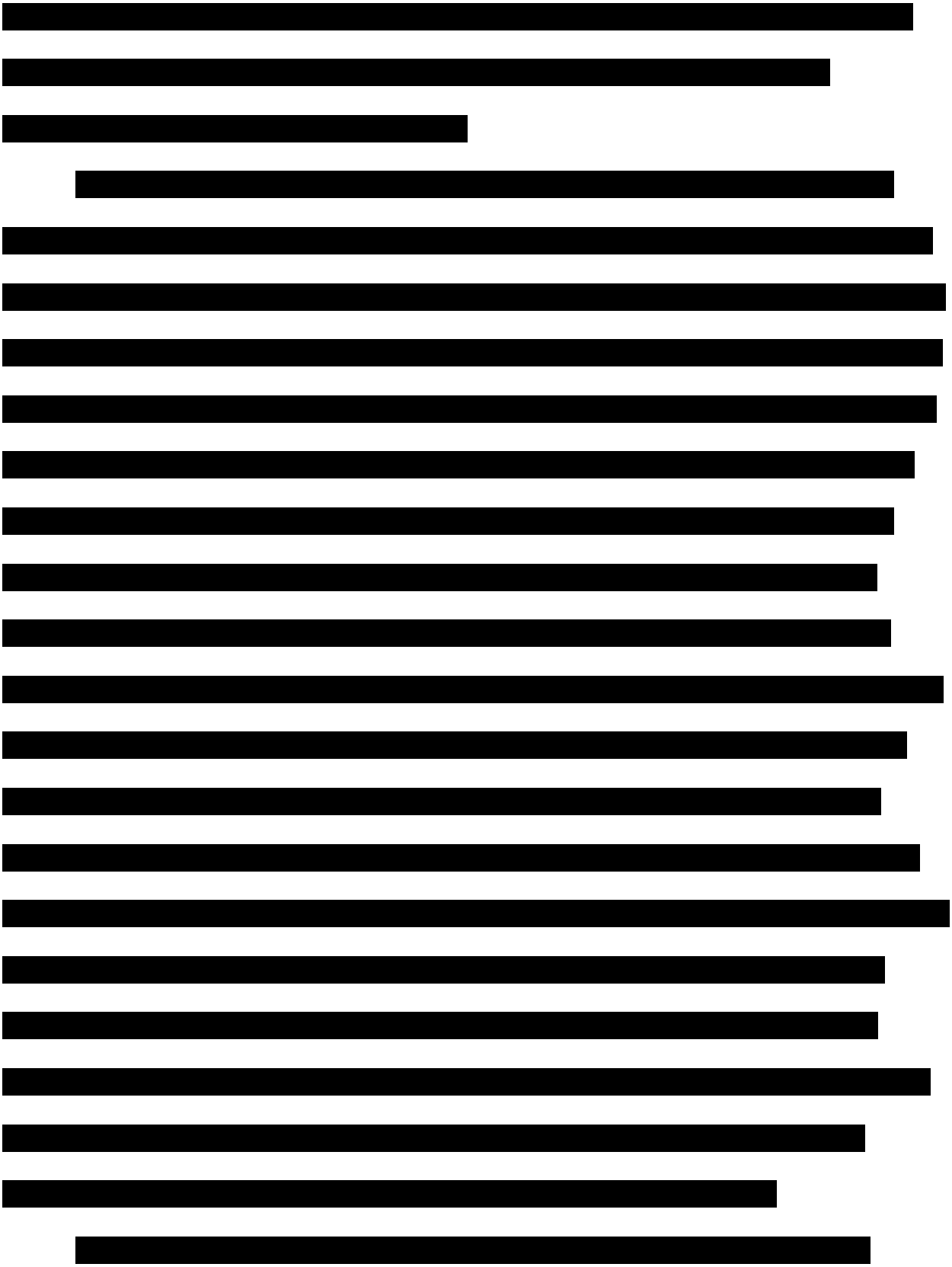
[redacted]

1009.3 The provisions guarantee that MCED test developers will have a consistent quality of supply because, as newer products of higher quality are released, they must be made available to customers. (RX6002 (Guerin-Calvert Trial Dep. at 61).)

Response to Finding No. 1009.3

The proposed finding is vague because it fails to define or describe what the phrases "consistent quality of supply" and "newer products of higher quality" mean. The proposed finding is vague because it fails to define or describe how Illumina's Open Offer provisions "very directly address the foreclosure concerns." [redacted]

[redacted]



[redacted]

1009.4 The provisions specifically address the concern that Illumina could disadvantage GRAIL rivals by delaying access to products because they level the playing field for customers and prevent individual customers from lagging behind in terms of what products are available to them. (RX6002 (Guerin-Calvert Trial Dep. at 61–62).)

Response to Finding No. 1009.4

The proposed finding is vague because it does not explain or describe how the Open Offer provides a "level the playing field for customers," "delaying access," or "prevent[s] individual customers from lagging behind in terms of" products available. The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). [redacted]

[redacted]

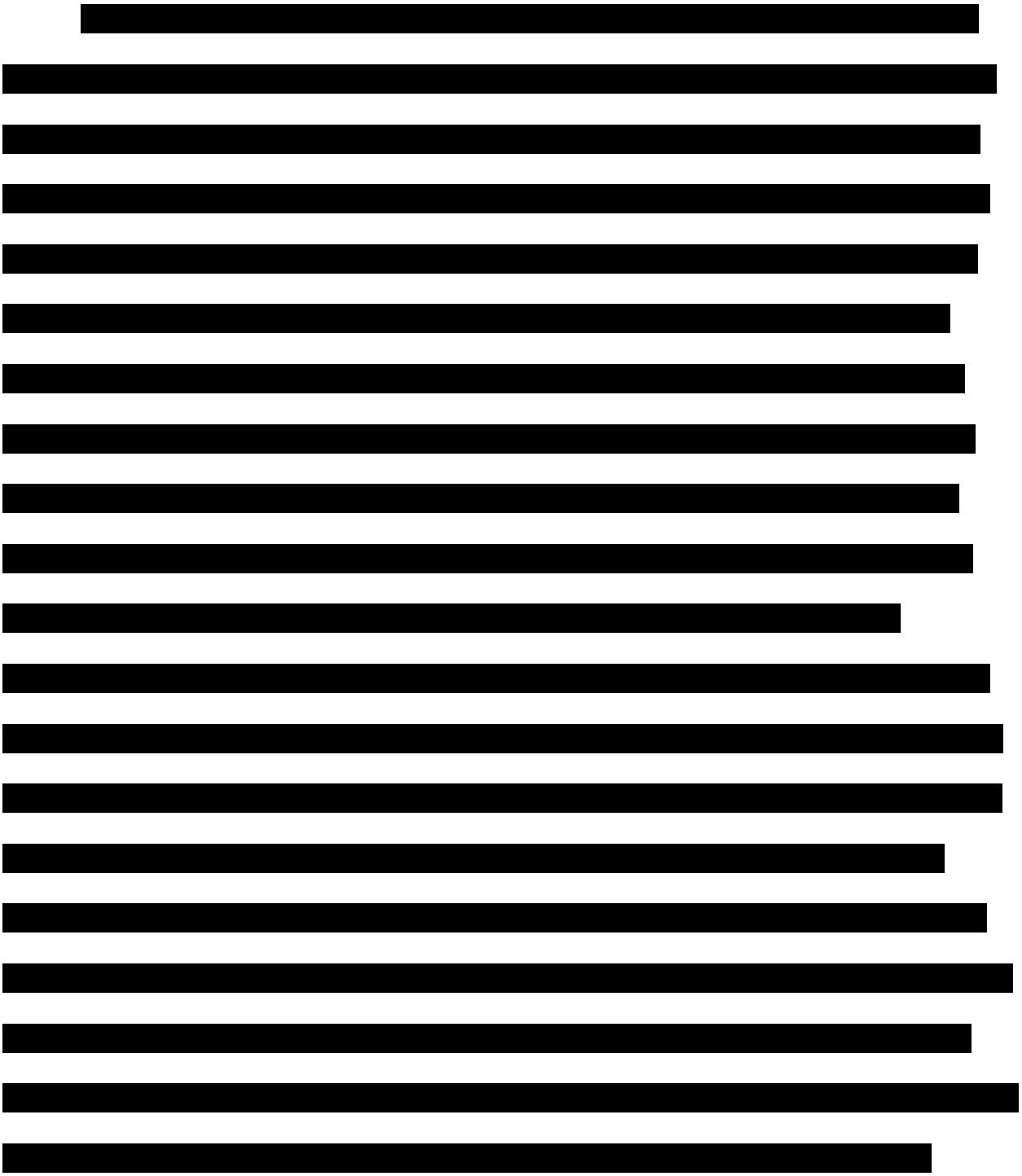
[redacted]

1010. In addition to the provisions requiring equivalent access to products, the Open Offer requires Illumina to enter into development agreements, on customers' requests, to design or modify Illumina's products to optimize interoperability with customers' tests. (Berry (Illumina) Tr. 881; PX0064 (Illumina) at 6.)

Response to Finding No. 1010

The proposed finding is vague because it fails to define or describe what the phrases "development agreements" or "optimize interoperability" mean. Additionally, the proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americans, and the Open Offer Signatory, Nicole Berry. Respondents do

not cite to any customers that are actually subject to the terms of the Open Offer. Instead, the evidence shows that the actual customers subject to the terms of the Open Offer testified that they do not think the development agreement provision addresses their concerns.



[redacted]

[redacted]

1010.1 The Open Offer requires that "Illumina shall enter into, upon Customer request, a separate development agreement with Customer on commercially reasonable terms, relating to the design or modification of any Supplied Product, in a manner that optimizes interoperability with Customer's tests, including, without limitation, capabilities, performance, speed, efficiency, cost, convenience, accuracy, specificity, precision, ease of use and user experience." (PX0064 (Illumina) at 6.)

Response to Finding No. 1010.1

[redacted]

[redacted]

1010.2 The development agreement term was added based on a specific request from FMI to incorporate this type of clause into an agreement. (Berry (Illumina) Tr. 881.)

Response to Finding No. 1010.2

The proposed finding is vague because it fails to define or describe the "specific request" it is referring to. Additionally, the proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americans, and the Open Offer Signatory, Nicole Berry. Respondents do not cite to any testimony from FMI executives to support its "fact."

[redacted]

[redacted]

1010.3 Illumina typically has not entered into such separate development agreements with any customers. (Berry (Illumina) Tr. 844, 882.) [redacted]

Response to Finding No. 1010.3

[redacted]

[redacted]

[redacted]

1010.4 Customers typically develop their tests without Illumina's developmental assistance or any optimization support with respect to their sequencing instruments or consumables. (Berry (Illumina) Tr. 844–47; *see, e.g.*, [redacted]

Response to Finding No. 1010.4

[redacted]

[redacted]

[redacted]

1010.5 Customers do not typically come to Illumina for advice on the development of their assays. (Berry (Illumina) Tr. 844.)

Response to Finding No. 1010.5

This proposed finding is vague and misleading. The terms typically and advice are vague in this context and are not defined. The proposed finding is also misleading to the extent it purports to speak to customer behavior but cites only the self-serving testimony of an Illumina executive.

The proposed finding is misleading to the extent it implies that Illumina customers do not need or want Illumina's assistance to develop their tests. MCED customers need Illumina's assistance throughout the developmental process of their test. [redacted]

[redacted]

1010.6 Illumina typically does not provide support in the development or commercialization of its customers' products. (Berry (Illumina) Tr. 846–47.)

Response to Finding No. 1010.6

This proposed finding is vague and misleading. It is vague because the terms "typically" and "support" are unclear and undefined. The proposed finding is also misleading because it ignores Ms. Berry's testimony that Illumina supports customers with troubleshooting and with

"the parts of the workflow that [Illumina] provide[s]." (Berry (Illumina) Tr. 846).

The proposed finding is misleading to the extent it implies that Illumina customers do not need or want Illumina's assistance to develop their tests. MCED customers need Illumina's assistance throughout the developmental process of their test. [redacted]

Additionally, [redacted]

[redacted]

1010.7 Customers typically purchase Illumina equipment and reagents "off the shelf" and do not commission Illumina to make custom sequencing equipment. (Berry (Illumina) Tr. 845; [redacted]

Response to Finding No. 1010.7

[redacted]

[redacted]

1010.7.1 Customers *prefer* to develop their tests on their own because they do not want to share key algorithms or analyses used to analyze the genetic data—*i.e.*, the "secret sauce"—with Illumina. (*See* Berry, Tr. 679.)

Response to Finding No. 1010.7.1

The proposed finding is vague because it fails to define or describe what "key algorithms or analyses" and the "secret sauce" include.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents do not cite to any customers for the statement of what "customers prefer."

[redacted]

1010.7.2 [redacted]

[redacted]

Response to Finding No. 1010.7.2

[redacted]

[redacted]

[redacted]

1010.8 Although Illumina does not typically enter into separate development agreements, the development agreement provision was added to the Open Offer to accommodate, in a customer-friendly way, the possible categories of requests that Illumina might be likely to receive over a 12–year period. (Berry (Illumina) Tr. 882.)

Response to Finding No. 1010.8

The proposed finding is vague because it fails to define or describe what the phrases "typically enter," "separate development agreements," or "customer-friendly way" mean. Nowhere in Illumina's Open Offer is the term "customer-friendly way" defined or used. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). The proposed finding is vague because it fails to define or describe what "possible categories of requests" Illumina be receive over a 12-year period.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents do not cite to any customer testimony or internal documents to support the "fact" that Illumina does not typically enter into separate development agreements." Also, Respondents do not cite to any customer testimony or internal documents to support the "fact" that the Open

Offer's development agreement provision was added to accommodate, in a customer-friendly way, the categories of requests that Illumina might receive over a 12-year period.

[redacted]

[redacted]

1010.9 The development agreement term works with the term on access to Pre-Release Sequencing Products to prevent Illumina from materially advantaging GRAIL or materially disadvantaging GRAIL's rivals because customers will be notified of any Pre-Release Sequencing Products and can pursue a development agreement to optimize interoperability of their tests with those products. (RX6002 (Guerin-Calvert Trial Dep. at 70–71).)

Response to Finding No. 1010.9

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite Guerin-Calvert as the only source of evidence supporting the proposed finding in contravention of this Court's Order. Further, it constitutes improper legal conclusion by an expert witness. The Court should disregard this evidence.

The proposed finding should further be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). This proposed finding is also misleading because the term "materially advantaging" is unclear and undefined.

The proposed finding is misleading to the extent it implies that the Open Offer's development plan and access to pre-released sequencing products prevent Illumina from disadvantaging Grail's rivals because customers will be notified of any Pre-Release Sequencing Products and can pursue a development agreement to optimize interoperability of their tests with those products. It is unclear whether a customer will know when a pre-released sequencing product is provided to a customers. [redacted] Even Illumina's executive and Open Offer signatory, Ms. Berry testified that Illumina's customers would not know whether they have access to prerelease products at the same time as Grail "unless Illumina proactively communicated such." (Berry (Illumina) Tr. 701). Therefore, this

Court should disregard the proposed finding.

1010.10 The development agreement term not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own competitive products. (RX6002 (Guerin-Calvert Trial Dep. at 68).)

Response to Finding No. 1010.10

The proposed finding is vague because it fails to define or describe what "disadvantaging GRAIL rivals, "act in a particular way," or "support rivals developing their own competitive products" means. The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer testimony stating that the Open Offer's development agreement "prevents Illumina from disadvantaging GRAIL rivals" and "requires Illumina to act in a particular way to support rivals developing their own competitive products. Instead, the evidence shows that the actual customers subject to the terms of the Open Offer testified that they have concerns about the Open Offer's development agreement provision. [redacted]

[redacted]

[redacted]

1011. The Open Offer forbids Illumina (under the "no-obsolescence term") from discontinuing products that any oncology customer has purchased in the prior year. (Rabinowitz (Natera) Tr. 421–22; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted]

Response to Finding No. 1011

[redacted]

[redacted]

[redacted]

1011.1 The Open Offer requires that "Illumina shall not discontinue any Supplied Product so long as Customer continues to purchase that Supplied Product. Illumina may discontinue a Supplied Product that Customer has not purchased in more than one year." (PX0064 (Illumina) at 6.)

Response to Finding No. 1011.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

> 1011.2 Illumina will ensure compliance with this provision through comprehensive recordkeeping, which makes it easy for Illumina to know which products customers are buying. (Berry (Illumina) Tr. 885.)

Response to Finding No. 1011.2

This proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. This proposed finding is also vague because it is unclear what

Respondents mean by "comprehensive records" and that phrase is not defined.

The term "ensure" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

1011.3 Before the Open Offer, there were no prohibitions on Illumina discontinuing any of its sequencing products. (Berry (Illumina) Tr. 883–84.)

Response to Finding No. 1011.3

This proposed finding is misleading to the extent it implies that prior to the Open Offer, there were no terms governing the discontinuation of a product. Ms. Berry testified that even before the Open Offer, Illumina had "some specific notification periods for products we were planning to obsolesce." (Berry (Illumina) Tr. 883).

The proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the

Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer have changed. [redacted]

1011.4 The no-obsolescence term was introduced into the Open Offer to ensure that customers did not feel they were being forced to transition to a new product, even if that new product was better and cheaper. (Berry (Illumina) Tr. 884–85.) The term commits Illumina to supporting older platforms even if Illumina develops newer platforms. [redacted]

Response to Finding No. 1011.4

[redacted]

[redacted]

[redacted]

[redacted]

1011.5 The addition of the no-obsolescence term represents a significant change and improvement from the premerger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 71–73).)

Response to Finding No. 1011.5

The proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer have changed. [redacted]

1011.6 Dr. Sean George, the Chief Executive Officer of Invitae, testified that Illumina's commitment to provide long-term continued access to Illumina products is reassuring for customers. (PX7081 (George (Invitae) Dep. at 59).) [redacted]

[redacted]

Response to Finding No. 1011.6

[redacted]

[redacted]

[redacted]

1011.7 The no-obsolescence provision of the Open Offer adequately addresses the concern often raised by economists in vertical transactions that an upstream firm could advantage its affiliate by simply no longer providing a product. (RX6002 (Guerin-Calvert Trial Dep. at 71–72).)

Response to Finding No. 1011.7

The proposed finding is vague because it fails to define or describe what "adequately addresses" means. Additionally, this proposed finding is vague because it fails to define or explain which "economists" it is referring to.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite Guerin-Calvert as the only source of evidence supporting the proposed finding in contravention of this Court's Order. Further, it constitutes improper legal conclusion by an expert witness. The Court should disregard this evidence.

The proposed finding should further be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

The proposed finding is also inherently speculative and misleading. It purports to speak to the concerns of all economists while relying solely on the testimony of Respondents' paid expert. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the witness's base conjecture, this proposed finding of fact should be disregarded.

1011.8 The no-obsolescence term interacts with the pricing terms of the Open Offer by ensuring that customers are "certainly no worse off than in the current world" and are actually better off because they are assured continued availability of products and no price increases. (RX6002 (Guerin-Calvert Trial Dep. at 72–73).)

Response to Finding No. 1011.8

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customers which have raised concerns over the no-obsolescence provision.

[redacted]

[redacted]

[redacted]

1012. Under the Open Offer, if Illumina experiences a supply shortage, it must allocate the existing supply in an equitable manner among its customers, including GRAIL and other affiliates. (Berry (Illumina) Tr. 885–86; PX0064 (Illumina) at 9.)

Response to Finding No. 1012

The proposed finding is vague because it fails to define or describe what "supply shortage" mean and what would qualify as a "supply shortage" Nor does the Open Offer or Respondents' amended Open Offer terms, presented in the middle of trial, define what constitutes a "supply shortage." (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); *see also* RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is vague because it fails to define or describe what an "equitable manner" means.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents do not cite to any customers that are actually subject to the Open Offer. MCED customers are concerned about supply shortage. [redacted]

[redacted]

1012.1 The Open Offer requires that "[i]n the event Illumina is experiencing a supply shortage of the applicable Supplied Product (or components therein), Illumina will allocate the existing supply in an equitable manner among its customers (including Affiliates) based on expiring lots, and which shall not favor Affiliates over other customers." (PX0064 (Illumina) at 9.)

Response to Finding No. 1012.1

The proposed finding is vague because "equitable manner" is undefined in this "fact" and in the Open Offer and its amended terms which were presented in the middle of trial. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); *see also* RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). Additionally, the proposed finding is vague because "expiring lots" is undefined in this "fact" and in the Open Offer and its amended terms. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); *see also* RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. [redacted]

[redacted]

1012.2 Illumina can ensure compliance with this provision because it tracks its supply when there is a supply shortage. (Berry (Illumina) Tr. 886–87.)

Response to Finding No. 1012.2

This proposed finding is inherently speculative, confusing, unsupported, and misleading. This proposed finding is inherently speculative because it relies solely on the unfounded, self-serving testimony of an Illumina executive that is uncorroborated by any ordinary course documents or analysis. It is further confusing, unsupported, and misleading to the extent it

implies that tracking supply shortages will ensure that Illumina complies with a contract term regarding how that supply is distributed. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is vague because it fails to define or describe what a "supply shortage" means. The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents do not cite to any customers that are actually subject to the Open Offer. MCED customers are concerned about supply shortage. [redacted]

The proposed finding is misleading to the extent it implies that Illumina knows how it will "allocate the existing supply in an equitable manner among its customers" if a supply shortage were to occur. Respondents' own expert Ms. Guerin-Calvert testified that she had not seen any documents or testimony that spells out how Illumina intends to allocate short supply among its customers. (RX6002 (Guerin-Calvert Trial Dep. at 154-55)).

Ultimately, even with the Open Offer's supply shortages provision, [redacted]

The term "ensure" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

To the extent this finding purports to interpret a contract term, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

> 1012.3 Under the Open Offer, Illumina cannot disadvantage a customer in the event of a short supply relative to GRAIL. (Berry (Illumina) Tr. 886.)

Response to Finding No. 1012.3

This proposed finding is vague, inherently speculative, and misleading. This proposed finding is inherently speculative because it relies solely on the unfounded, self-serving testimony of an Illumina executive that is uncorroborated by any ordinary course documents or customer testimony. The proposed finding is vague because it is unclear what is meant by

"disadvantage[ing]" a customer.

The proposed finding is vague because it fails to define or describe what "short supply" means and what would qualify as a "supply shortage." Nor does the Open Offer or Respondents' amended Open Offer terms, presented in the middle of trial, define what constitutes a "supply shortage." (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); *see also* RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents do not cite to any customers that are actually subject to the Open Offer. MCED customers are concerned about supply shortage. [redacted]

The proposed finding is misleading to the extent it implies that Illumina knows how it will "allocate the existing supply in an equitable manner among its customers" if a supply shortage were to occur. Respondents' own expert Ms. Guerin-Calvert testified that she had not seen any documents or testimony that spells out how Illumina intends to allocate short supply among its customers. (RX6002 (Guerin-Calvert Trial Dep. at 154-55)).

Ultimately, even with the Open Offer's supply shortages provision, [redacted]

[redacted]

The proposed finding is also misleading to the extent it implies that Illumina will do what is best for all its customers. The weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

Additionally, Illumina does not care much about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-

based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore, this Court should disregard the proposed finding.

To the extent this finding purports to interpret a contract term, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

> 1012.4 Under the premerger status quo, Illumina would be able to allocate short supply to GRAIL or to customers who were willing to pay the highest price. (RX6002 (Guerin-Calvert Trial Dep. at 76–77).) The short supply provision of the Open Offer addresses this concern by providing for an equitable manner of allocation. (RX6002 (Guerin-Calvert Trial Dep. at 77).) It also ensures that customers with the greatest need—those whose lots are expiring the earliest—will receive allocations of short supply first. (RX6002 (Guerin-Calvert Trial Dep. at 77).)

Response to Finding No. 1012.4

The proposed finding is vague because it fails to define or describe what "short supply" means and what would qualify as a "supply shortage." Nor does the Open Offer or Respondents' amended Open Offer terms, presented in the middle of trial, define what constitutes a "supply shortage." (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); *see also* RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is vague because it fails to define or describe what an "equitable manner" means.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents do not cite to any customers that are actually subject to the Open Offer. MCED customers are concerned about supply shortage. [redacted]

[redacted]

[redacted]

The proposed finding is misleading to the extent it implies that Illumina knows how it will "allocate the existing supply in an equitable manner among its customers" if a supply shortage were to occur. Respondents' own expert Ms. Guerin-Calvert testified that she had not seen any documents or testimony that spells out how Illumina intends to allocate short supply among its customers. (RX6002 (Guerin-Calvert Trial Dep. at 154-55)).

Ultimately, even with the Open Offer's supply shortages provision, [redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite Guerin-Calvert as the only source of evidence supporting the proposed finding in contravention of this Court's Order. Further, it constitutes improper legal conclusion by an expert witness. The Court should disregard this evidence.

To the extent this finding purports to interpret a contract term, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

This proposed finding is misleading to the extent it purports to speak to the concerns of Illumina's customers but relies solely on the speculative, self-serving testimony of Respondents'

paid expert.

The proposed finding is also misleading to the extent it implies that Illumina will do what is best for all its customers. The weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted]. Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted].

Additionally, Illumina does not care much about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-

based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")). Therefore, this Court should disregard the proposed finding.

4. **Pricing**

1013. The Open Offer requires Illumina to treat customers equitably relative to GRAIL and any other For-Profit Entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.)

Response to Finding No. 1013

This proposed finding is vague, misleading, and constitutes improper legal conclusion. The term equitable is vague and is not defined here or in the Open Offer.

The term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted].

The proposed finding is also misleading to the extent it implies that Illumina will do what

is best for its customers. The weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted]. Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted].

The proposed finding is also misleading to the extent it implies that Illumina customers will know what other customers are purchasing. Even Illumina's executive and Open Offer signatory, Ms. Berry testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)). Certain information, such as a customer's order information and service reports, is confidential and one customer would not have access to another customer's information). (PX7076 (Berry (Illumina) Dep. at 81; 291)). Ms. Berry testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)). Therefore, this Court should disregard the proposed finding. Therefore, this Court should disregard the proposed finding.

To the extent the cited testimony purports to interpret the word "equitable," the proposed

finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

1014. Customers may select one of two options for each product purchased under the Open Offer: the pricing that they received before Illumina's acquisition of GRAIL closed ("Grandfathered Pricing") or pricing under a universal pricing grid ("Universal Pricing".) (PX0064 (Illumina) at 7.)

Response to Finding No. 1014

Complaint Counsel has no specific response to this finding.

1014.1 Grandfathered Pricing under the Open Offer is "any pricing (either under a quote of duration longer than 30 days or a supply agreement) that is operative for the Customer for use of the Supplied Products at the time that the Transaction closes, provided that this pricing is for ongoing, ordinary course purchases of Supplied Products." (PX0064 (Illumina) at 4.)

Response to Finding No. 1014.1

This proposed fact is vague and misleading. The term "ongoing, ordinary course purchases" is unclear and undefined here and in the Open Offer. Additionally, the proposed finding is vague because "operative" is undefined.

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, as [redacted]

[redacted].

> 1014.2 Universal Pricing under the Open Offer refers to "the Volume-Based Net Price for [any given] Supplied Product in accordance with Appendix 1" of the Open Offer. (PX0064 (Illumina) at 7.) "The universal pricing grid in Appendix 1 contains all currently available universal pricing, including list prices and volume-based discount tiers, for currently available Supplied Products, and [the Open Offer requires that] such Appendix 1 will be updated as additional pricing tiers or new Supplied Products (including new versions of existing Supplied Products) become available." (PX0064 (Illumina) at 7.) "Volume-Based Net Price" refers to "the actual list price of a Supplied Product less the applicable discount for a customer's volume under a volume-based discount schedule." (PX0064 (Illumina) at 5.)

Response to Finding No. 1014.2

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the bracketed language in the proposed finding is not reflective of the text of the Open Offer. To the extent the bracketed language purports to interpret the Open Offer, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Further, as [redacted]

[redacted]

1014.3 The Open Offer requires that "Customer will be able to select one of two options for each Supplied Product that they purchase under this Supply Agreement. Customer may elect to receive the Grandfathered Pricing that Customer received before the close of the Transaction under 5.a. . . . Alternatively, Customer may elect to switch over to receiving Universal Pricing under 5.b, under which Customer purchases each Supplied Product under the pricing in Appendix 1." (PX0064 (Illumina) at 7.)

Response to Finding No. 1014.3

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

1014.4 Customers can pick Grandfathered Pricing for some products and Universal Pricing for others. (Berry (Illumina) Tr. at 892.)

Response to Finding No. 1014.4

This proposed finding is unsupported and constitutes improper legal opinion. It presents an interpretation of the Open Offer based solely on the self-serving testimony of an Illumina executive. Further, the proposed finding purports to interpret the Open Offer, and therefore should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

The proposed finding is misleading to the extent it implies that because customers have the option of Grandfathered Pricing or Universal Pricing that customer concerns are resolved regarding the Open Offer's pricing provisions. MCED customers have testified to their concerns about Illumina's Open Offer pricing provisions. First and foremost, Illumina customers will have no way to know the pricing Grail or any other customer receives from Illumina. [redacted]

Third, customers are concerned that the Open Offer's pricing provision does not provide

MCED customers the lowest pricing. [redacted]

1014.5 The ability to choose on a product-by-product basis presents benefits over the premerger status quo because it gives customers added flexibility on pricing. (RX6002 (Guerin-Calvert Trial Dep. at 37).)

Response to Finding No. 1014.5

This Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Ms. Guerin-Calvert as the only source of evidence supporting this proposed fact in contravention of this Court's Order. The Court should disregard this evidence.

This proposed fact is also speculative and unsupported to the extent it speaks to what is beneficial for Illumina's customers but relies solely on the self-serving testimony of Respondents' paid expert.

This proposed finding is also vague and confusing because it refers to "benefits" but lists only one purported benefit and provides no explanation or basis for that assertion.

The proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the Acquisition, Illumina contracted with customers at arms-length.

[redacted]

1015. If a customer chooses Grandfathered Pricing, it will have the option of maintaining the pricing it had prior to the Illumina-GRAIL transaction for the duration of the 12–year term of the Open Offer. (Berry (Illumina) Tr. 889–90, 902–03; PX0064 (Illumina) at 7.)

Response to Finding No. 1015

The proposed finding is misleading to the extent it implies that maintaining MCED customer pricing terms they had pre-acquisition means that the Open Offer restores the loss of competition that will take place post-acquisition.

Prior to the Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer have changed. [redacted]

1015.1 The Open Offer requires that Illumina allow any "Customer" to "continue to receive the benefit of any Grandfathered Pricing for the Term." (PX0064 (Illumina) at 7.)

Response to Finding No. 1015.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. [redacted]

1015.2 The Grandfathered Pricing option was included because some customers may have the view that their current (pre-merger) pricing was more favorable for a particular product than the price offered in the Open Offer. (Berry (Illumina) Tr. 889–

90.) Grandfathered Pricing was included to give customers the option to keep their legacy price. (Berry (Illumina) Tr. 889–90.)

Response to Finding No. 1015.2

The proposed finding is vague because it fails to define or describe who the phrase "some customers" includes.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and Open Offer signatory, Nicole Berry. Respondents cite to no customer testimony to support their "fact" that the Grandfathered Pricing option was included because of the views "some customers may have." Additionally, the proposed finding is misleading to the extent it implies that maintaining MCED customer pricing terms they had pre-acquisition means that the Open Offer restores the loss of competition that will take place post-acquisition.

Moreover, Respondents admit that some customers may have been able to achieve "more favorable pricing for a particular product than the price offered in the Open Offer." This amplifies the deficiencies in the non-negotiated, unilateral Open Offer because, as a remedy, the terms of the Open Offer will be imposed on all of Illumina's MCED customers regardless of whether they could have achieved more favorable terms from Illumina absent the Acquisition. Therefore, this Court should disregard the proposed finding.

1015.3 If an existing customer uses Grandfathered Pricing, their prices would not increase during the 12–year term, and, provided that they continue to purchase those products, the products themselves would not be discontinued. (Berry (Illumina) Tr. 902–03.) The Open Offer requires this because of the interaction between the Grandfathered Pricing provision and the no-obsolescence provision: The no-obsolescence provision prohibits Illumina from discontinuing or rendering obsolete any Supplied Product, and the Grandfathered Pricing provision ensures that customers can continue to receive their legacy pricing over the full 12–year term. (Berry (Illumina) Tr. 902–03; PX0064 (Illumina) at 6–7.)

Response to Finding No. 1015.3

[redacted]

1016. If a customer chooses Universal Pricing, that customer will receive the standard pricing in Illumina's Universal Pricing grid. (PX0064 (Illumina) at 7.)

Response to Finding No. 1016

The proposed finding is vague because it fails to define or describe what "Illumina's Universal Pricing grid" is**.** [redacted]

1016.1 The Open Offer requires that "[i]f Customer is not receiving Grandfathered Pricing for a Supplied Product, Customer shall receive the Volume-Based

Net Price for that Supplied Product in accordance with Appendix 1." (PX0064 (Illumina) at 7.) Appendix 1 provides the Universal Pricing grid. (PX0064 (Illumina) at 12–27.)

Response to Finding No. 1016.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. [redacted]

[redacted]

1016.2 [redacted]

Response to Finding No. 1016.2

[redacted]

[redacted]

[redacted]

1016.3 The purpose of providing the Universal Pricing grid was to be transparent around the prices that GRAIL and other For-Profit Entities pay for the products and services it buys from Illumina. (deSouza (Illumina) Tr. 2403.)

Response to Finding No. 1016.3

The proposed finding is vague because it fails to define or describe what "transparent" means.

The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza. Respondents do not cite to any documentary evidence or customer testimony to support this "fact." The proposed finding is misleading to the extent it implies that Illumina included the Universal Pricing grid only because it wanted to be transparent on pricing.

The proposed finding is misleading to the extent it implies that Illumina's pricing grid is actually "universal" or transparent. Illumina pricing grid is not universal because customer have the ability to receive discretionary discounts. [redacted] It is this discretionary discounts which determines the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)). While the Open Offer purports to equalize the volume-based discounts that

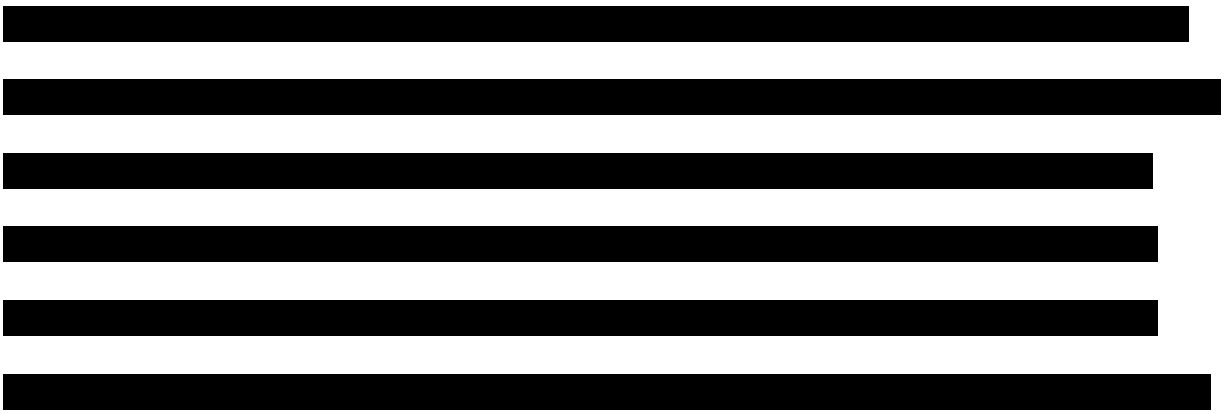
MCED test developers may receive for certain levels of sales, the Open Offer does nothing to account for these discretionary discounts. As Illumina's SVP and General Manager of the Americas, and signatory to the Open Offer, Ms. Berry, testified, under the Open Offer, customers are only eligible to receive discretionary discounts for activities that are considered "short term projects" as defined in the Open Offer, meaning the activities fall *outside* of the normal course of business. (Berry (Illumina) Tr. 925; PX0064 at 008 (Illumina Open Offer agreement, dated March 30, 2021)). Therefore, this Court should disregard the proposed finding.

> 1016.4 The Universal Pricing grid will be helpful to customers as they create multiyear business plans because they will know what prices they can access. (deSouza (Illumina) Tr. 2403, 2439.)

Response to Finding No. 1016.4

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza. Respondents do not cite to any customer testimony to support the "fact" that the Universal Pricing grid will be helpful to customers as they create multiyear business plans."



[redacted]

1016.5 GRAIL receives pricing under the Universal Pricing grid. (Berry (Illumina) Tr. 894.)

Response to Finding No. 1016.5

[redacted]

[redacted]

[redacted]

1016.6 Under Universal Pricing, customers will know with certainty that they are not disadvantaged relative to GRAIL or anyone else in the market. (deSouza (Illumina) Tr. 2403–04.)

Response to Finding No. 1016.6

The proposed finding is misleading and against the weight of the evidence to the extent it implies that customer will know what pricing Grail is receiving. [redacted]

1016.7 The Universal Pricing grid directly addresses the concern that Illumina could treat GRAIL more favorably in terms of pricing. (RX6002 (Guerin-Calvert Trial Dep. at 37–38).)

Response to Finding No. 1016.7

The proposed finding is misleading to the extent it implies that the Universal pricing grid resolves customers concerns that Illumina can favor Grail and disadvantage Grail rivals with regards to pricing. Illumina's pricing grid does not resolve the concern that Illumina customers will have no way to monitor what pricing Grail receives in order to enforce the Open Offer pricing provisions. [redacted]

[redacted]

1017. If a customer chooses Universal Pricing, it will receive "most favored nation" (MFN) pricing protections relative to Equivalent customers. (Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

Response to Finding No. 1017

The proposed finding is misleading to the extent it implies that customers will know whether they are actually receiving "most-favored nation (MFN) pricing protections relative to Equivalent customers." MCED customers will not know what pricing other customers, including Grail, are receiving from Illumina. [redacted] Even Respondents own executive and Open Offer signatory, Ms. Berry, testified that customers "would not know what prices other customers are paying. That's considered confidential information." (Berry (Illumina) Tr. 700)) [redacted]

Moreover, the Open Offer's MFN provisions provide no pricing protections related to

discounts separate and apart from volume-based discounts. The MFN provisions provide that customers shall have access to "Volume-Based Net Prices" that are no less favorable than the Volume-Based Net Prices that Grail, or equivalent customers, receive. *See* (PX0064 at 006 (Illumina, Open offer Letter, Mar. 29, 2021)). "Volume-Based Net Prices" means "the actual list price of a Supplied Product less the applicable discount for a customer's volume under a volume-based discount table." (PX0064 at 003 (Illumina, Open offer Letter, Mar. 29, 2021)). [redacted] Ultimately, it is this discretionary discounts which determines the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)). So while the Open Offer purports to equalize the volume-based discounts that MCED test developers may receive for certain levels of sales, the Open Offer does nothing to account for these discretionary discounts. Therefore, this Court should disregard the proposed finding.

> 1017.1 The Open Offer requires that "[i]f Customer is not currently receiving Grandfathered Pricing for Supplied Product, . . . Customer shall have access to Volume-Based Net Prices (under Appendix 1) for that Supplied Product that are no less favorable (i.e., the same or better) than the Volume-Based Net Prices provided by Illumina to an Equivalent customer after the date the Transaction closes, for that Supplied Product." (PX0064 (Illumina) at 8.)

Response to Finding No. 1017.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

The proposed finding is misleading to the extent it implies that customers will know whether they are actually receiving pricing that is "no less favorable (i.e., the same or better) than the Volume-Based Net Prices provided by Illumina to an Equivalent customer." MCED customers will not know what pricing other customers, including Grail, receive from Illumina.

[redacted]

[redacted] Ultimately, it is this discretionary discounts which determines the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)). So while the Open Offer purports to equalize the volume-based discounts that MCED test developers may receive for certain levels of sales, the Open Offer does nothing to account for these discretionary discounts. Therefore, this Court should disregard the proposed finding.

1017.2 "'Equivalent' means, with respect to the comparison of Customer to another customer, that (a) the aggregate volume of all Supplied Products purchased by

such other customer from Illumina in the immediately preceding year (measured in U.S. dollars) is not more than 10% greater than the volume purchased by Customer in prior year, (b) such other customer is a For-Profit Entity, and (c) such other customer is not currently receiving Grandfathered Pricing." (PX0064 (Illumina) at 3; *see also* Berry (Illumina) Tr. 895.)

Response to Finding No. 1017.2

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, as [redacted]

To the extent the cited testimony purports to interpret the Open Offer, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

1017.3 Illumina has a contract with Deloitte Consulting to operationalize the terms of the Open Offer, including the MFN terms. (*See* Berry (Illumina) Tr. 800, 894–96.) Deloitte will help guarantee Illumina's compliance with the Open Offer provisions and ensure that Illumina is prompt in upholding its obligations under the agreement. (Berry (Illumina) Tr. 896–97; PX7135 (Rock Dep. at 90).) As part of its work with

> Illumina, Deloitte will help translate the definition of Equivalent customer to processes that allow Illumina to operationalize the Equivalent customer MFN term. (Berry (Illumina) Tr. 896–97.)

Response to Finding No. 1017.3

The proposed finding is vague because "operationalize," "prompt," "translate" are undefined. The proposed finding is also vague because it fails to explain or describe how Deloitte will "help guarantee Illumina's compliance with the Open Offer provisions."

It is unclear what Respondents mean by "[a]s part of its work with Illumina, Deloitte will help translate the definition of Equivalent customer to processes that allow Illumina to operationalize the Equivalent customer MFN term." If Respondents are using Deloitte to help "translate" what Equivalent customer means under the Open Offer it would seem that Illumina does not know what "equivalent customer" means under its own agreement. Thus, how can customers properly rely on the Open Offer to protected themselves from Illumina's incentive to disadvantage Grail's rivals if the meaning or use of "equivalent customer" is undecided. The proposed finding also reveals the inadequacy and insufficiency of the Open Offer as it admits that Respondents have yet to operationalize the Open Offer, despite the Open Offer becoming operative at the time the Acquisition closed on August 18, 2021, prior to trial. (*See* Op. Stmt. (Resp.) Tr. 84-85; deSouza (Illumina) Tr. 2234; Bishop (Grail) Tr. 1353; Berry (Illumina) Tr. 857); (PX0064 at 003 (Illumina, Open offer Letter, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding.

> 1017.4 If an Equivalent customer received a discretionary discount higher than the discounts in Appendix 1 for equivalent volume or a price that is lower than the prices in Appendix 1 for an equivalent volume, then Illumina would be obligated to reduce the price for other customers at the same volume levels to match the prices under such discretionary discount. (Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39).)

Response to Finding No. 1017.4

The proposed finding is inaccurate. The Open Offer's MFN provisions provide no pricing protections related to discounts separate and apart from volume-based discounts. The MFN provisions provide that customers shall have access to "Volume-Based Net Prices" that are no less favorable than the Volume-Based Net Prices that Grail, or equivalent customers, receive. *See* (PX0064 at 006 (Illumina, Open offer Letter, Mar. 29, 2021)). "Volume-Based Net Prices" means "the actual list price of a Supplied Product less the applicable discount for a customer's volume under a volume-based discount table." (PX0064 at 003 (Illumina, Open offer Letter, Mar. 29, 2021)). [redacted] Ultimately, it is this discretionary discounts which determines the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)). So while the Open Offer purports to equalize the volume-based discounts that MCED test developers may receive for certain levels of sales, the Open Offer does nothing to account for these discretionary discounts.

The proposed finding is misleading to the extent it implies that customers will know whether they are actually receiving the same pricing and discounts as "Equivalent customers." [redacted]

[redacted] Even Respondents own executive and Open Offer signatory, Ms. Berry, testified that customers "would not know what prices other customers are paying. That's considered confidential information." (Berry (Illumina) Tr. 700)) [redacted] Therefore, this Court should disregard the proposed finding.

1018. If a customer chooses Universal Pricing, it will also receive MFN pricing protections relative to GRAIL. (Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

Response to Finding No. 1018

[redacted]

[redacted] Even Respondents own executive and Open Offer signatory, Ms. Berry, testified that customers "would not know what prices other customers are paying. That's considered confidential information." (Berry (Illumina) Tr. 700)). [redacted]

Therefore, this Court should disregard the proposed finding.

> 1018.1 The Open Offer requires that "[i]f Customer is not currently receiving Grandfathered Pricing for Supplied Product, Customer shall have access to Volume-Based Net Prices (under Appendix 1) for that Supplied Product that are no less favorable (i.e., the same or better) than the Volume-Based Net Prices provided to GRAIL (including of transfer pricing, portability fees, and royalties), after the date the Transaction closes, for that Supplied Product." (PX0064 (Illumina) at 8.)

Response to Finding No. 1018.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

[redacted]

1018.2 Now that GRAIL is part of Illumina, it receives pricing under the Universal Pricing grid. (Berry (Illumina) Tr. 894.)

Response to Finding No. 1018.2

The proposed finding is misleading to the extent it implies that pricing Grail pays to Illumina would be anything more than an accounting entry. Now that Illumina owns Grail it is unclear what prices Grail would actually have to pay since Grail is owned by Illumina. At best, the fees paid by Grail would simply be an accounting matter.

MCED customers as well as Illumina and Grail executive agree that post-acquisition the

prices and fees Grail pays to Illumina becomes an accounting matter. [redacted]

Illumina and Grail's executives agree that post-acquisition Grail's purchase of Illumina products will be no more than an accounting entry. Illumina's CEO, Mr. deSouza, testified that the price at which Grail purchases products from Illumina represents the price at which one Illumina entity purchases from another. (deSouza (Illumina) Tr. 2465). The price Illumina charges to its Grail subsidiary for consumables and sequencers will have no net impact on the combined entity's net P&L. (deSouza (Illumina) Tr. 2467-68; 2469-70). Grail's own Vice President of Finance, Aaron Freidin, testified that while he does not know how Illumina will account for Grail's purchases of Illumina products, he does know "that it's all eliminated and you end up with a true cost at the end when you report your financials as a public company." (Freidin (Grail) Tr. 3153). Respondents' economic expert, Dr. Carlton, likewise testified that "GRAIL doesn't technically pay a price. If you want to make up a scenario in which you force GRAIL to 'pay some price,' and you call that a transfer price . . . I'm happy to make that assumption." (RX6000 (Carlton Trial Dep. at 141-42)). Therefore, this Court should disregard

the proposed finding.

> 1018.3 If GRAIL receives a discretionary discount higher than the discounts in Appendix 1 for equivalent volume or a price that is lower than the prices in Appendix 1 for an equivalent volume, then Illumina would be obliged to reduce the price for other customers at the same volume levels to match the prices under such discretionary discount. (Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39).)

Response to Finding No. 1018.3

This proposed finding is inherently speculative and unsupported. The proposed finding is inherently speculative because it relies solely on the self-serving testimony of an Illumina executive and Respondents' paid expert.

The term "obliged" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

To the extent the proposed finding purports to interpret the Open Offer, it also proffers an improper legal conclusion in contravention of this Court's order and the Part 3 rules, and should be disregarded. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

To the extent the proposed finding relies on Ms. Guerin-Calvert's testimony as factual support it should be disregarded because it violates this Court's order that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3.)

[redacted]

[redacted] Ultimately, it is this discretionary discounts which determines the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)). So while the Open Offer purports to equalize the volume-based discounts that MCED test developers may receive for certain levels of sales, the Open Offer does nothing to account for these discretionary discounts. Therefore, this Court should disregard the proposed finding.

1018.4 Customers testified that the MFN pricing protections would help mitigate their concerns with the merger if properly executed. (*See* PX7077 (Chahine (Helio) Dep. at 114–15); PX7081 (George (Invitae) Dep. at 60–61).) [redacted]

Response to Finding No. 1018.4

[redacted]

[redacted]

[redacted]

1019. If GRAIL or an Equivalent customer receives more favorable pricing than another customer, the Open Offer requires Illumina to notify the other customer promptly and to refund any difference between the price paid by the customer and the applicable reduced price. (Berry (Illumina) Tr. 894, 914; PX0064 (Illumina) at 8.)

Response to Finding No. 1019

The proposed finding is vague because it fails to define or describe what "more favorable pricing" and "promptly" mean.

[redacted]

[redacted]

1019.1 Specifically, the Open Offer requires that, in the event that GRAIL or an Equivalent customer receives more favorable pricing, "Illumina will notify Customer promptly, and no later than 45 days after the end of the applicable Illumina fiscal quarter, and the pricing made available to Customer for the applicable Supplied Products will be reduced, effective as of the date on which GRAIL or the Equivalent customer received the triggering pricing, and Customer will receive such reduced pricing for the period of time that the triggering pricing is available to GRAIL or the Equivalent customer. With respect to units of Supplied Product ordered and invoiced pursuant to a Purchase Order accepted after the date the triggering purchase was made, and for which Customer has paid the applicable invoice, Illumina will refund to Customer the difference between the pricing made available to Customer and the triggering pricing, multiplied by the number of affected units of Supplied Product." (PX0064 (Illumina) at 8.)

Response to Finding No. 1019.1

This proposed finding is vague because the term "promptly" is unclear and undefined.

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

[redacted]

1020. The Grandfathered Pricing, Universal Pricing and MFN provisions represent an improvement over the status quo for customers. (RX6002 (Guerin-Calvert Trial Dep. at 42–44); *see also* [redacted]

Response to Finding No. 1020

[redacted]

[redacted]

1020.1 For nearly all MCED test customers, the Open Offer Universal Pricing is superior than their current agreement prices. (RX6002 (Guerin-Calvert Trial Dep. at 43–44).) Additionally, for any current pricing that is superior under a current agreement, customers may opt for Grandfathered Pricing. (Berry (Illumina) Tr. 889–90; PX0064 (Illumina) at 7.) [redacted]

Response to Finding No. 1020.1

[redacted]

[redacted]

1020.2 An MCED test developer that currently pays list price would also receive benefits under these provisions. (RX6002 (Guerin-Calvert Trial Dep. at 44).) They have the benefit of being able to opt into a supply agreement subject to the Universal Pricing grid, should they so choose. (RX6002 (Guerin-Calvert Trial Dep. at 44).) They also

have the benefit of receiving improved discounts as their volume grows. (RX6002 (Guerin-Calvert Trial Dep. at 44).)

Response to Finding No. 1020.2

The proposed finding is misleading to the extent it implies that MCED test developers view the Open Offer pricing provisions as a "benefit." Respondents cite to no customers who are actually subject to the Open Offer to support this "fact." Instead, Respondents rely solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert.

Further, the proposed finding is an improper use of an expert. This Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert in contravention of this Court's Order to support the fact that MCED customers "benefit" from the Open Offer's pricing provisions. *See* Order on Post-Trial Findings at 3. This Could should disregard this evidence.

The proposed finding is misleading to the extent it implies that customers "have the benefit of receiving improved discounts as their volume grows." The Open Offer's MFN provisions provide no pricing protections related to discounts separate and apart from volume-based discounts. The MFN provisions provide that customers shall have access to "Volume-Based Net Prices" that are no less favorable than the Volume-Based Net Prices that Grail, or equivalent customers, receive. *See* (PX0064 at 006 (Illumina, Open offer Letter, Mar. 29, 2021)). "Volume-Based Net Prices" means "the actual list price of a Supplied Product less the applicable discount for a customer's volume under a volume-based discount table." (PX0064 at 003 (Illumina, Open offer Letter, Mar. 29, 2021)). [redacted]

[redacted] Ultimately, it is this discretionary discounts which determines the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)). So while the Open Offer purports to equalize the volume-based discounts that MCED test developers may receive for certain levels of sales, the Open Offer does nothing to account for these discretionary discounts. Therefore, this Court should disregard the proposed finding.

1020.3 [redacted]

Response to Finding No. 1020.3

[redacted]

[redacted]

1021. In addition to the Grandfathered Pricing, Universal Pricing and MFN terms, the Open Offer commits Illumina not to increase prices beyond inflation for the 12–year term of the agreement (*i.e.*, the "no-price-increase provision".) (Rabinowitz (Natera) Tr. 433; Berry (Illumina) Tr. 899; Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted]

Response to Finding No. 1021

[redacted]

[redacted]

[redacted]

1021.1 The Open Offer requires that "[t]he inflation-adjusted (based on the Bureau of Labor Statistics' Analytical Laboratory Instrument Manufacturing Index in the Producer Price Index ("PPI")) Volume-Based Net Price (under Appendix 1) that Customer has access to for each Supplied Product purchased under this Supply Agreement over the twelve (12) year term of this Supply Agreement shall not increase. To the extent Illumina's costs of goods sold for a Supplied Product materially increase due to factors beyond Illumina's control, then the Volume-Based Net Price (under Appendix 1) may increase solely to reflect that cost increase and solely for the duration of that cost increase." (PX0064 (Illumina) at 7.)

Response to Finding No. 1021.1

This proposed finding is vague because the terms "materially increase" and "factors beyond Illumina's control" are unclear and not defined. It is unclear what amounts to a material increase and what is considered "beyond Illumina's control." Additionally, it is unclear who gets to make this determination.

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "required" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. [redacted]

> 1021.2 This commitment not to raise prices applies to all potential GRAIL rivals, including any companies that may develop products similar to the Galleri test. (Aravanis (Illumina) Tr. 1926.)

Response to Finding No. 1021.2

This proposed finding is inherently speculative and unsupported. The proposed finding is inherently speculative because it relies solely on the self-serving testimony of an Illumina executive. To the extent the proposed finding purports to interpret the Open Offer, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

The term "commitment" is misleading to the extent it implies that Illumina cannot breach

the terms of the Open Offer. [redacted]

> 1021.3 The no-price-increase provision applies whether a customer is using Grandfathered Pricing or Universal Pricing. (Berry (Illumina) Tr. 902; PX0064 (Illumina) at 7.)

Response to Finding No. 1021.3

This proposed finding is inherently speculative because it is not included in the relevant Open Offer term and therefore is supported solely by the self-serving testimony of an Illumina executive. Further, to the extent the proposed finding purports to interpret the Open Offer, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

The proposed finding is misleading to the extent it implies that prohibiting price increases resolves customer concerns that Illumina will have the incentive to disadvantage Grail's rivals. Additionally, the proposed finding is misleading to the extent it implies that a prohibition against

price increases will provide customers the best pricing. [redacted]

[redacted]

1021.4 The no-price-increase provision was not available to customers prior to the Open Offer. (Berry (Illumina) Tr. 900–01.)

Response to Finding No. 1021.4

This proposed finding is misleading because it omits Ms. Berry's testimony that prior to the Open Offer, "there were some supply agreements that had . . . annual price caps that related to the amount by which Illumina would be permitted to increase prices on an annual basis." (Berry (Illumina) Tr. 900).

The proposed finding is misleading to the extent it implies that the Open Offer is sufficient because it provides customers with terms they have not had in the past. Prior to the Acquisition, Illumina contracted with customers at arms-length. Post-Acquisition, Illumina is now interacting with customers as rivals and the incentives behind how Illumina treats customer have changed. (*See* CCFF ¶¶ 3079-3188) [redacted]

[redacted]

The proposed finding is misleading to the extent it implies that prohibiting price increases resolves customer concerns that Illumina will have the incentive to disadvantage Grail's rivals. Additionally, the proposed finding is misleading to the extent it implies that a prohibition against price increases will provide customers the best pricing. [redacted]

[redacted]

1021.5 [redacted]

Response to Finding No. 1021.5

[redacted]

[redacted]

1021.6 [redacted]

Response to Finding No. 1021.6

[redacted]

1022. Under the Open Offer, Illumina cannot release a new version of a Supplied Product at a higher price than the previous version, unless the new version results in a material improvement in performance or capability. (Berry (Illumina) Tr. 901–02.)

Response to Finding No. 1022

The proposed finding is vague because it fails to define or describe what "material improvement in performance and capability" means and nowhere in the Open Offer is the term "material improvement in performance or capability" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "material improvement in performance or capability" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry.

The proposed finding is misleading to the extent it implies that the Open Offer's "New Product Pricing" provision resolves MCED customers concerns. [redacted]

[redacted]

1022.1 The Open Offer requires that "[t]o the extent that Illumina launches a new version of any Supplied Product (e.g., a sequencing instrument of similar throughput, or a Sequencing Consumable of the same sequencing read length and similar number of sequencing reads per flow cell), the inflation-adjusted (based on the PPI) Volume-Based Net Price per gigabase of sequencing shall not be higher as compared to the Volume-Based Net Price of the prior version of the Supplied Product, provided that the new version of the Supplied Product does not result in any material improvements in performance or capability." (PX0064 (Illumina) at 7.)

Response to Finding No. 1022.1

[redacted]

1022.2 The Open Offer also requires that "[t]he price for a new Supplied Product or a new version of a materially improved Supplied Product must be commercially reasonable. For any materially improved Supplied Product, the price of the new version must take into account the value of the improvement. For avoidance of doubt, in any arbitration in which the price of a new version of a Supplied Product or a new Supplied Product is disputed, the arbitrator is empowered to determine the reasonableness of the price, including the value of the any improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer." (RX3935 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2408.)

Response to Finding No. 1022.2

The proposed finding is vague because it fails to define or describe the terms "materially improved," "commercial reasonable," "value of the improvement," "improvement in performance or capability," and "commensurate with the improvement." Additionally, nowhere

in the Open Offer or the additional terms of the Open Offer are these terms defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is misleading to the extent it implies that an arbitration resolves concerns over the Open Offer's new product supplied provision. [redacted] Additionally, the "protection of arbitration does not resolve customers concerns. Arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Mr. Getty also testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into."

(PX7105 (Getty (Guardant) Dep. at 95)).

Ultimately, as Mr. Getty testified "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)).

Complaint Counsel acknowledges that Respondents' amended Open Offer letter, presented in the middle of trial, includes the quoted language. The term "requires," however is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As

[redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after

the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1022.3 The new-product-pricing provision does not obligate customers to switch to a new product. (RX6002 (Guerin-Calvert Trial Dep. at 47).) If a customer did not agree that there was a material improvement in performance or capability of a new version of a Supplied Product, they could stay with their existing product. (RX6002 (Guerin-Calvert Trial Dep. at 48).) Alternatively, if a customer felt that there was a material improvement in performance or capability, but that this improvement did not justify a new price, the customer could take this issue directly to Illumina or to arbitration. (RX6002 (Guerin-Calvert Trial Dep. at 48).)

Response to Finding No. 1022.3

The proposed finding is vague because it fails to define or describe what "material improvement in performance and capability" means and nowhere in the Open Offer is the term "material improvement in performance or capability" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "material improvement in performance or capability" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). Thus, if customers have no way to know what constitutes a "material improvement in performance or capability" of a new product how can they (1) disagree with Respondents and "stay with their existing product and (2) prove to the arbiter that a new price is not justified.

The proposed finding is misleading to the extent it implies that an arbitration resolves concerns over the Open Offer's new product supplied provision. [redacted]

[redacted] Additionally, the "protection of arbitration does not resolve customers concerns. Arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Mr. Getty also testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)).

Ultimately, as Mr. Getty testified "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). Therefore, this Court should

disregard the proposed finding.

1023. Under the Open Offer, Illumina also agrees that by 2025, it will continue its pre-merger approach to reducing sequencing pricing and reduce the pricing of sequencing by at least 43%, regardless of whether a customer is receiving Grandfathered Pricing or Universal Pricing. [redacted]; Berry (Illumina) Tr. 712–13, 897, 903–04; Conroy (Exact/Thrive) Tr. at 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted]

Response to Finding No. 1023

[redacted]

[redacted]

[redacted]

[redacted]

1023.1 Specifically, the Open Offer provides that "by 2025, Illumina commits that, under this Supply Agreement, the Volume-Based Net Price (under Appendix 1) to Customer per gigabase of sequencing using the highest throughput Illumina instrument then available, with the highest throughput, best-performance flow cell and kit then available, at full capacity, will be at least 43% lower than the inflation-adjusted (based on the PPI) Volume-Based Net Price (under Appendix 1 as of March 26, 2021), per gigabase of sequencing using the NovaSeq instrument, with an S4 300 flow cell, at full capacity." (PX0064 (Illumina) at 7.)

Response to Finding No. 1023.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. [redacted]

[redacted]

[redacted]

[redacted]

1023.2 Sequencing involves analyzing the nucleotides, or bases, of DNA or RNA in a sample. (*See* Berry (Illumina) Tr. 818–20; PX8399 (Henry (PacBio) Decl.) at 1.) A gigabase is one million DNA or RNA bases. (PX7076 (Berry (Illumina) Dep. at 265).) Sequencing flow cells are described in terms of the number of gigabases of DNA or RNA that can be sequenced. (Berry (Illumina) Tr. 904–05.) Thus, describing the price reduction using a price per gigabase nomenclature allows for normalizing different capacity flow cells and comparing different kits' pricing on an "apples-to-apples basis". (Berry (Illumina) Tr. 905; *see also* RX6002 (Guerin-Calvert Trial Dep. at 43).)

Response to Finding No. 1023.2

This proposed finding is misleading to the extent it purports to speak to the benefits of certain pricing methodology because it is based solely on the self-serving testimony of an Illumina executive and Respondents' paid expert. Further, to the extent this finding relies on Ms. Guerin-Calvert's deposition testimony, it violates this Court's order that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3).

The proposed finding is vague because it fails to define or describe what "normalizing" means.

[redacted]

[redacted]

1023.3 While the number of gigabases refers to a number of DNA or RNA bases, a "read" refers to the processing of a fragment of DNA or RNA. (*See* Berry (Illumina) Tr. 818–20; PX8399 (Henry (PacBio) Decl.) at 1–2.) Thus, if Illumina reduced price per gigabase of the S4 300 flow cell by 43%, it would also reduce the price per read by 43% because the given number of reads in that S4 300 flow cell kit is constant. (Berry (Illumina) Tr. 923.)

Response to Finding No. 1023.3

This proposed finding is misleading to the extent it purports to speak to the benefits or effects of certain pricing methodology because it is based solely on the self-serving testimony of an Illumina executive. It is also misleading because it omits Ms. Berry's testimony that the Open Offer does not commit to a price reduction for price per read. (Berry (Illumina) Tr. 923).

[redacted]

[redacted]

[redacted]

1023.4 By reducing price per gigabase, Illumina will also reduce a customer's price per sample on an absolute linear basis, presuming that the customer's assay does not change in terms of the amount of sequencing required for that sample. (Berry (Illumina) Tr. 905–06.)

Response to Finding No. 1023.4

This proposed finding is vague and misleading. The term "absolute linear basis" is unclear and undefined. This proposed finding is misleading and speculative to the extent it purports to speak to the benefits or effects of certain pricing methodology because it is based solely on the self-serving testimony of an Illumina executive.

The proposed finding relies solely upon the self-serving testimony of Illumina's own executive and Open Offer signatory, Nicole Berry, and fails to cite to any customer testimony supporting this "fact."

[redacted]

[redacted]

1023.5 The price-reduction provision is intended to commit Illumina to a significant price reduction by January 1, 2025. (Berry (Illumina) Tr. 711–12.)

Response to Finding No. 1023.5

This proposed finding is vague because the term "significant" is unclear and undefined.

The proposed finding is misleading to the extent it implies that Illumina's intention "to commit Illumina to a significant price reduction by January 1, 2025" is written into the terms of the Open Offer.

The proposed finding is misleading to the extent it implies that the Open Offer's price-reduction provisions actually commit Illumina to a significant price reduction. The Open Offer states that Illumina's "Volume-Based Net Price to Customer per gigabase of sequencing using the highest throughput Illumina instrument then available… will be at least 43% lower…" (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021)).

[redacted]

[redacted]

1023.6 Illumina selected the 43% number because that is the price Illumina assumed in its deal model that GRAIL would pay in 2025. (deSouza (Illumina) Tr. 2338; [redacted] Illumina also chose this number by considering both what customers wanted and what Illumina could achieve. (Berry (Illumina) Tr. 907–08; Aravanis (Illumina) Tr. 1868.)

Response to Finding No. 1023.6

[redacted]

[redacted]

1023.7 Although the Offer requires "at least" a 43% price reduction by January 1, 2025, Illumina intends to try to achieve that goal faster. (Aravanis (Illumina) Tr. 1868.)

Response to Finding No. 1023.7

The proposed finding is vague because it fails to define or describe what the terms "goal," "faster," and "intends to try to achieve" means. It is unclear how much "faster" Illumina "intends to try to achieve" of a 43% price reduction.

The proposed finding is misleading to the extent it implies the terms Illumina's Open Offer states that "Illumina intends to try to achieve that goal faster." Nowhere in the Open Offer, or its amended terms, does Illumina make this commitment. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021); RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is misleading to the extent it implies that there will actually be a price decrease of 43 percent to MCED customers. Specifically, the proposed finding is incomplete because Respondents omit that the 43 percent discount is only off the price per gigabase of sequencing, and it is misleading because a reduction in price per gigabase is irrelevant to MCED test developers. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)). Respondents use "price per gigabase" instead of price per read which is the most appropriate measure of price for liquid biopsy MCED tests. The ability to read one gigabase is equal to one billion nucleotides. Because cfDNA fragments are typically fewer than

200 base pairs long, there is no advantage to a flow cell that can read more than 200 base pairs. *See* (CCFF ¶ 292). [redacted] Thus, even comparing two different flow cells on the same sequencer shows that cost per gigabase does not correlate with cost per read. Put another way, by releasing the 300-base version of the NovaSeq S4 flow cell kit, Illumina could say it lowered the sequencing cost per gigabase by 35 percent (from $6.46 to $4.80), but in reality it simultaneously increased the cost per million reads by 12 percent (from $1.29 to $1.44). Thus, Respondents' commitment that the Open Offer

reduces price of sequencing by 43 percent per gigabase could ultimately result in a price *increase* (or, at the very least, far less than a 43 percent price decrease) to MCED test developers. Therefore, this Court should disregard the proposed finding.

> 1023.8 The 43% discount still applies even if, in 2025, the highest throughput flow cell has a material improvement in performance or capability. (Berry (Illumina) Tr. 908.)

Response to Finding No. 1023.8

The proposed finding is vague because it fails to define what a "material improvement in performance or capability" means and who gets to determine this.

The proposed finding is misleading to the extent it implies that there will actually be a price decrease of 43 percent to MCED customers. Specifically, the proposed finding is incomplete because Respondents omit that the 43 percent discount is only off the price per gigabase of sequencing, and it is misleading because a reduction in price per gigabase is irrelevant to MCED test developers. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)). Respondents use "price per gigabase" instead of price per read which is the most appropriate measure of price for liquid biopsy MCED tests. The ability to read one gigabase is equal to one billion nucleotides. Because cfDNA fragments are typically fewer than 200 base pairs long, there is no advantage to a flow cell that can read more than 200 base pairs. *See* (CCFF ¶ 292). [redacted]

[redacted] Thus, even comparing two different flow cells on the same sequencer shows that cost per gigabase does not correlate with cost per read. Put another way, by releasing the 300-base version of the NovaSeq S4 flow cell kit, Illumina could say it lowered the sequencing cost per gigabase by 35 percent (from $6.46 to $4.80), but in reality it simultaneously increased the cost per million reads by 12 percent (from $1.29 to $1.44). Thus, Respondents' commitment that the Open Offer reduces price of sequencing by 43 percent per gigabase could ultimately result in a price *increase* (or, at the very least, far less than a 43 percent price decrease) to MCED test developers. Therefore, this Court should disregard the proposed finding.

> 1023.9 Illumina cannot avoid its obligation under the 43% reduction provision by changing what it defines as a new product because Illumina's minimum obligation is to reduce the price of the NovaSeq S4 300 flow cell. (Berry (Illumina) Tr. 908–09.)

Response to Finding No. 1023.9

The phrase "cannot avoid" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

The proposed finding is misleading to the extent it implies that there will actually be a price decrease of 43 percent to MCED customers. Specifically, the proposed finding is incomplete because Respondents omit that the 43 percent discount is only off the price per gigabase of sequencing, and it is misleading because a reduction in price per gigabase is irrelevant to MCED test developers. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)). Respondents use "price per gigabase" instead of price per read which is the most appropriate measure of price for liquid biopsy MCED tests. The ability to read one gigabase is equal to one billion nucleotides. Because cfDNA fragments are typically fewer than 200 base pairs long, there is no advantage to a flow cell that can read more than 200 base pairs. *See* (CCFF ¶ 292). [redacted]

[redacted] Thus, even comparing two different flow cells on the same sequencer shows that cost per gigabase does not correlate with cost per read. Put another way, by releasing the 300-base version of the NovaSeq S4 flow cell kit, Illumina could say it lowered the sequencing cost per gigabase by 35 percent (from $6.46 to $4.80), but in reality it simultaneously increased the cost per million reads by 12 percent (from $1.29 to $1.44). Thus, Respondents' commitment that the Open Offer reduces price of sequencing by 43 percent per gigabase could ultimately result in a price *increase* (or, at the very least, far less than a 43 percent price decrease) to MCED test developers.

Therefore, this Court should disregard the proposed finding.

1023.10 Illumina's track record shows that it has consistently sought to drive down pricing through innovation. (Berry (Illumina) Tr. 714–15; [redacted] Indeed, since Illumina entered the sequencing market in the mid-2000s, it has dramatically driven down the price of sequencing. (Berry (Illumina) Tr. 810–11.) Illumina lowered genomics pricing so dramatically that a writer in Forbes coined the term "Flatley's Law" to describe the price reduction achieved during the tenure of Illumina's former Chief Executive Officer, Jay Flatley. (Berry (Illumina) Tr. 810–11.)

Response to Finding No. 1023.10

[redacted]

[redacted]

[redacted]

1023.11 The price-reduction term directly addresses the foreclosure concerns that have been raised by providing a specific pricing commitment for the price of the highest throughput, best performance product on a specific future date. (RX6002 (Guerin-Calvert Trial Dep. at 49).)

Response to Finding No. 1023.11

The proposed finding is vague because it fails to define or describe what "foreclosure concerns" and "specific pricing commitment" it is referring to. The proposed finding is vague because it fails to define what "price-reduction term" it is referring to.

The proposed finding is misleading to the extent it implies that the Open Offer's pricing provisions resolve customer concerns that post-acquisition Illumina has the incentive to disadvantage Grail's rivals. MCED customers have testified to their concerns regarding the Open Offer's pricing provisions.

MCED customers testified to their concern over whether there will actually be a price decrease of 43 percent. The 43 percent discount is only off the price per gigabase of sequencing, and MCED customers testified that a reduction in price per gigabase is irrelevant to MCED test developers. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)). Respondents use "price per gigabase" instead of price per read which is the most appropriate measure of price for liquid biopsy MCED tests. The ability to read one gigabase is equal to one billion nucleotides. Because cfDNA fragments are typically fewer than 200 base pairs long, there is no advantage to a flow cell that can read more than 200 base pairs. *See* (CCFF ¶ 292). [redacted]

[redacted]

[redacted]

MCED customers testified to their concern over whether there will actually be a price decrease of 43 percent. The 43 percent discount is only off the price per gigabase of sequencing, and MCED customers testified that a reduction in price per gigabase is irrelevant to MCED test developers. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)). Respondents use "price per gigabase" instead of price per read which is the most appropriate measure of price for liquid biopsy MCED tests. The ability to read one gigabase is equal to one billion nucleotides. Because cfDNA fragments are typically fewer than 200 base pairs long, there is no advantage to a flow cell that can read more than 200 base pairs. *See* (CCFF ¶ 292).

[redacted]

[redacted]

[redacted]

1023.12 The price-reduction term represents an improvement over the status quo because the price reduction is contractually guaranteed. (RX6002 (Guerin-Calvert Trial Dep. at 52); *see* [redacted]

Response to Finding No. 1023.12

[redacted]

[redacted]

[redacted]

1023.13 [redacted]

Response to Finding No. 1023.13

[redacted]

1024. A customer who signs the Open Offer can receive short-term project pricing that is the same or better than pricing extended to GRAIL or equivalent customers for similar projects. (PX0064 (Illumina) at 8.) Illumina is also required to notify customers of short-term pricing granted to GRAIL. (PX0064 (Illumina) at 8.)

Response to Finding No. 1024

The proposed finding is vague because it fails to define what "short-term project" means. The Open Offer provides a definition for "short-term project" but that definition is also vague as it states that a short term project "means a project or circumstance giving rise to a discrete purchase of Sequencing Consumables outside of ongoing ordinary course of purchases…" (PX0064 (Illumina) at 004 (Open Offer Definition of Short Term Project, Mar. 29, 2021)). It is unclear what type of "project or circumstance" would qualify under this definition. Additionally,

the proposed finding is vague because it fails to define what "similar projects" means. The Open Offer states that a customers "Short Term Project" must be "substantially similar in size (i.e., using between 90% and 110% of the volume of Sequencing Consumables) and duration (i.e., for a period of not more than 3 months longer than the other Short Term Project)…" ((PX0064 (Illumina) at 008 (Open Offer § 5h Short Term Projects, Mar. 29, 2021)).). It is unclear whether "similar projects" in this finding means "substantially similar" as defined in the Open Offer and it is also unclear who gets to decide whether a customer's project is similar.

The proposed finding is misleading to the extent it implies customers will know what short term pricing Grail receives from Illumina. MCED customers will have no way to know what pricing Grail is received from Illumina. [redacted]

Even Illumina's own executive and Open Offer signatory, Ms. Nicole Berry, testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)). Additionally, Ms. Berry testified that a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)). Therefore,

this Court should disregard the proposed finding.

> 1024.1 The Open Offer requires that "Customer shall have access to Short Term Project pricing that is no less favorable (*i.e.*, the same or better) than pricing extended to Equivalent customer or GRAIL for a Short Term Project of substantially similar size (*i.e.*, using between 90% and 110% of the volume of Sequencing Consumables) and duration (*i.e.*, for a period of not more than 3 months longer than the other Short Term Project), provided that Customer has requested such pricing. If Illumina offers GRAIL pricing for a Short Term Project under this section, Illumina shall make Customer aware of such pricing promptly, but in no event later than 45 days after the end of the applicable Illumina fiscal quarter." (PX0064 (Illumina) at 8.)

Response to Finding No. 1024.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. The term "requires," however is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. [redacted]

Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty

(Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1024.2 "'Short Term Project' means a project or circumstance giving rise to a discrete purchase of Sequencing Consumables outside of ongoing ordinary course of purchases made by a For-Profit Entity. The duration of a Short Term Project is no more than two years." (PX0064 (Illumina) at 4.)

Response to Finding No. 1024.2

Complaint Counsel acknowledges that this is the definition for "Short Term Project" provided in Illumina's Open Offer. However, the proposed finding and therefore the Open Offer's definition is vague because is unclear what type of "project or circumstance" would qualify under this definition. Additionally, the proposed finding is vague because it fails to define what "discrete purchase" means. Therefore, this Court should disregard the proposed finding.

> 1024.3 No customer, including GRAIL, can receive Short Term Project pricing for more than two consecutive years or for ordinary course purchases. (Berry (Illumina) Tr. 913; deSouza (Illumina) Tr. 2440; PX0064 (Illumina) at 8.) The Open Offer specifically provides that "[n]o customer, including GRAIL, may receive Short Term Project pricing for more than two consecutive years. No customer, including GRAIL, may use Short Term Project pricing for ongoing ordinary course purchases, including for its standard commercial testing." (PX0064 (Illumina) at 8.)

Response to Finding No. 1024.3

The proposed finding is misleading to the extent it implies that customers will know what pricing other customers are receiving from Illumina. [redacted]

[redacted] Even Illumina's own executive and Open Offer signatory, Ms. Berry, testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)). Ms. Berry also testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)).

The proposed finding is also misleading to the extent it implies that a customer receiving the same price as Grail means that the customer is receiving a low price. [redacted] The price at which Grail purchases products from Illumina represents the price at which one Illumina entity purchases from another. (deSouza (Illumina) Tr. 2465). The price Illumina charges to its Grail subsidiary for consumables will have no net impact on the combined entity's net P&L. (deSouza (Illumina) Tr. 2467-68). The price Illumina charges to its Grail subsidiary for sequencers will have no net impact on the combined entity's net P&L. (deSouza (Illumina) Tr. 2469-70). Grail's own Vice President of Finance, Aaron Freidin, testified that while he does not know how Illumina will account for Grail's purchases of Illumina products, he does know "that it's all eliminates and you end up with a true cost at the

end when you report your financials as a public company." (Freidin (Grail) Tr. 3153). Respondents' economic expert, Dr. Carlton, likewise testified that "GRAIL doesn't technically pay a price. If you want to make up a scenario in which you force GRAIL to 'pay some price,' and you call that a transfer price . . . I'm happy to make that assumption." (RX6000 (Carlton Trial Dep. at 141-42)). Therefore, this Court should disregard the proposed finding.

> 1024.4 The Short Term Project pricing provision was added because certain discrete situations arise where there is a good reason for a customer to pay less than the pricing in the universal grid or grandfathered pricing agreements. (Berry (Illumina) Tr. 909–10.) Short Term Project pricing was offered, for example, to support COVID-19 studies and in situations where Illumina offered to replace perished inventory, for example, from a freezer malfunctioning. (Berry (Illumina) Tr. 910–13.)

Response to Finding No. 1024.4

The proposed finding is vague because it fails to define or explain what "certain discrete situations" and "good reason" mean. It is unclear what type of situation would be considered a "discrete situation" and who gets to make this determination. Furthermore, nowhere in the Open Offer or its amended terms is such an answer provided. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021); RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding relies solely on the self-serving testimony of Illumina's own executive and Open Offer signatory, Ms. Berry, and fails to cite to any customer testimony or documentary evidence to support this "fact." Therefore, this Court should disregard the proposed finding.

> 1024.5 The Short Term Project pricing provision addresses the potential foreclosure concerns that have been raised because it allows for MFN pricing relative to GRAIL and Equivalent customers for Short Term Project needs. (RX6002 (Guerin-Calvert Trial Dep. at 44–45).)

Response to Finding No. 1024.5

The proposed finding is vague because it fails to define or describe what "foreclosure concerns" means. The proposed finding is vague because it fails to explain how the Open Offer's

"Short Term Project pricing provision addressees the potential foreclosure concerns that have been raised."

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry to support Respondents' proposed "fact."

The proposed finding is misleading to the extent it implies that the Open Offer's Short Term Project provision "allows for MFN pricing relative to GRAIL and Equivalent customers for Short Term Project needs." Even with the Short Term Project provisions and its accompanying definition, customers will have no way to know what products or pricing Grail receives from Illumina. [redacted] Even Illumina's own executive and Open Offer signatory, Ms. Berry, testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying

for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)). Ms. Berry also testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)). Thus, it is misleading for Respondents to claim that "the Short Term Project pricing provision addresses the potential foreclosure concerns that have been raised because it allows for MFN pricing relative to GRAIL…" when customers will have no way to know what products or pricing Grail receives from Illumina. Therefore, this Court should disregard the proposed finding.

1025. The Open Offer's pricing provisions, in their totality, address the foreclosure concerns that have been raised. (RX6002 (Guerin-Calvert Trial Dep. at 34–36).)

Response to Finding No. 1025

The proposed finding is vague and unsupported. The proposed finding is vague because Respondents fail to explain how the "totality" of the Open Offer's pricing provisions "address the foreclosure concerns." Additionally, the proposed finding is vague because it fails to cite what "foreclosure concerns" "have been raised."

The proposed finding is misleading to the extent it implies that the Open Offer's pricing provisions resolve customer concerns. MCED customers have testified to their various concerns over the Open Offer pricing provisions.

MCED customers will have no way to know what products or pricing Grail receives from Illumina. [redacted]

[redacted] Even Illumina's own executive and Open Offer signatory, Ms. Berry, testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)). Ms. Berry also testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)).

The Open Offer's "no price increase" term will not protect MCED customers against price increases or guarantee customers the best pricing. [redacted]

[redacted]

The Open Offer's "no price increase" term will not protect MCED customers against price increases or guarantee customers the best pricing. [redacted]

[redacted]

[redacted]

[redacted]

1025.1 The pricing provisions, in their totality, provide guarantees to potential MCED test developers that they will receive fair pricing from Illumina in the short term, medium term and long term. (RX6002 (Guerin-Calvert Trial Dep. at 53).) The provisions also treat customers fairly in terms of advance knowledge and information about pricing. (RX6002 (Guerin-Calvert Trial Dep. at 53).)

Response to Finding No. 1025.1

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry or any customer subject to the Open Offer to support Respondents' proposed "fact."

The proposed finding is vague because it fails to define what "fair pricing" means. Nowhere in the Open Offer or its amended term does it state that MCED test developers will receive "fair pricing" from Illumina.

The proposed finding is vague because it fails to define what "treat customers fairly in terms of advance knowledge and information about pricing" means. Here, Respondents are limiting the statement that customers are treated "fairly" only to "advance knowledge" and "information about pricing." Thus, it seems Respondents are stating that the Open Offer's pricing provisions do not "treat customers fairly" when it comes to pricing and products supplied by Illumina to Grail.

The proposed finding is misleading to the extent it implies that the Open Offer's pricing provisions "treat customers fairly in terms of advance knowledge and information about

pricing." MCED customers testified that under the Open Offer they have no way of knowing what products and pricing Grail or any other customer receives. [redacted] Even Illumina's own executive and Open Offer signatory, Ms. Berry, testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)). Ms. Berry also testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)).

The term "guarantees" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1025.2 [redacted]

Response to Finding No. 1025.2

[redacted]

[redacted]

1025.3 [redacted]

Response to Finding No. 1025.3

[redacted]

[redacted]

5. IVD Agreements and FDA Documentation

1026. The Open Offer provides that, for 6 years after the closing of the Illumina-GRAIL transaction (*i.e.*, until August 18, 2027), customers may enter into one or more separate agreements with Illumina to develop IVD test kits for use on Illumina's platforms. (Rabinowitz (Natera) Tr. 423–24; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted]

Response to Finding No. 1026

[redacted]

[redacted]

1026.1 The Open Offer requires that "Customer may enter into, at any time from today, effective as of the closing of the Transaction, until the sixth anniversary of the closing of the Transaction, an agreement with Illumina under which Customer may develop and commercialize in-vitro diagnostic ("IVD") test kits for use on Illumina's diagnostic ("Dx") sequencing platforms." (PX0064 (Illumina) at 8.)

Response to Finding No. 1026.1

Complaint Counsel acknowledges that the quoted language is provided in the Open Offer's FDA provision. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding the FDA provision. [redacted]

[redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

> 1026.2 To ensure transparency with potential partners, the types of IVD agreements available are posted on Illumina's website. (Goswami (Illumina) Tr. 3204–07.)

Response to Finding No. 1026.2

[redacted]

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any

customer testimony to support this "fact."

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding the FDA provision. [redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

[redacted]

The term "ensures" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1026.3 IVD agreements under the Open Offer allow for developers to create test kits for all oncology applications, including cancer screening generally and multicancer screening specifically. (Goswami (Illumina) Tr. at 3233–35; PX0064 (Illumina) at 34.)

Response to Finding No. 1026.3

The proposed finding is vague because it fails to define or explain what "oncology applications" means and includes.

The proposed finding is misleading to the extent it implies that the Open Offer resolves

customer concerns regarding the FDA provision. [redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

1026.4 Customers are investing in developing IVD test kits under the terms of these IVD agreements. (Goswami (Illumina) Tr. 3218–19.)

Response to Finding No. 1026.4

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony to support this statement about customer behavior.

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding the FDA provision. [redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

[redacted]

1026.5 Test developers do not need to enter into IVD agreements to pursue either LDTs or single-site PMAs. (Goswami (Illumina) Tr. 3273.)

Response to Finding No. 1026.5

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony to support this statement about customer behavior. It is unclear what Mr. Goswami's familiarity with the FDA is

The proposed finding is misleading to the extent it implies that customers do not need an agreement with Illumina to develop a distributed or IVD test. A distributed or "kitted" IVD is an IVD test that has received PMA approval from the FDA permitting analysis by independent testing providers, such as hospitals or large reference labs like LabCorp or Quest. (Goswami (Illumina) Tr. 3186-87; Leite (Illumina) Tr. 2150; PX7049 (Bailey (PGDx) IHT at 68-69); PX7063 (Berry (Illumina) IHT at 202); PX7112 (Bailey (PGDx) Dep. at 14-18); PX7093 (Young (Illumina) Dep. at 44)). MCED customers testified that having a distributed test will the in the future of their MCED tests in order to reach more patients. An agreement with Illumina is required to pursue such a distributed test. [redacted]

[redacted]

1027. The Open Offer requires Illumina to provide customers with standard terms for IVD agreements and to provide documentation to assist the customer with FDA approval or marketing authorization. (PX0064 (Illumina) at 8; PX7093 (Young Dep. at 68).)

Response to Finding No. 1027

The proposed finding is misleading to the extent it implies that the Open Offers "FDA" provision resolves customers concerns about Illumina's ability to limit their development of distributed IVD tests. [redacted]

[redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

The term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1027.1 The Open Offer requires that "Illumina will provide standard terms for Customer to enter into a stand-alone agreement to enable Customer to develop and commercialize IVD test kits on one or all of Illumina's Dx sequencing platforms. Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test using the Supplied Products." (PX0064 (Illumina) at 8.)

Response to Finding No. 1027.1

The proposed finding is vague because it and the Open Offer itself fail to define or describe what the terms "standard terms," "documentation," or "information" include. Additionally, the proposed finding is vague because it and the Open Offer itself fail to explain how "documentation or information" are to be determined as "*reasonably required* for Customer to seek FDA approval…" (emphasis added). It is unclear who will decide what qualifies as "reasonably required" documentation or information.

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. The term "requires," however is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1027.2 The Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; [redacted] Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PX0064 (Illumina) at 39; [redacted]

Response to Finding No. 1027.2

[redacted]

[redacted]

1027.3 Illumina may not withhold support of documentation and information for FDA approval even from a customer who is a cancer screening competitor. (Berry (Illumina) Tr. 914–16.)

Response to Finding No. 1027.3

The proposed finding is misleading to the extent it implies that Illumina cannot withhold documentation or information a customer needs for FDA approval. The Open Offer states that "Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test using the

Supplied Products." (PX0064 at 008) Thus, from the language in the Open Offer, Illumina can withhold documentation or information for a customer if such information is not considered "reasonably required." It is unclear what is "reasonably required" documentation or information and who gets to make this determination.

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding the FDA provision. [redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

[redacted]

The proposed finding is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1027.4 [redacted]

Response to Finding No. 1027.4

The proposed finding is misleading to the extent it implies that Thrive asking for FDA approval protections means that Thrive and other customers' concerns are resolved. [redacted]

The proposed finding is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1028. The Open Offer provides 3 template agreement options for customers interested in IVD test kit agreements: an All-Platforms Agreement, a NextSeq Agreement, and a NovaSeq Agreement. (Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 28–40.)

Response to Finding No. 1028

The proposed finding is misleading to the extent it implies that customers are able to negotiate the terms of an Illumina IVD agreement. [redacted]

Illumina customers testified to their minimal negotiating leverage with Illumina as Illumina is their sole supplier and there are no alternatives to switch to. For example, Singlera's Mr. Gao testified the Singlera has "[z]ero pretty much" negotiating leverage with Illumina. Mr. Gao continued "not only zero, in our heart we have a resentment kind of feel. Maybe Illumina will use this strategy to suppress us." (PX7042 (Gao (Singlera) IHT at 84-85). Additionally, [redacted]

[redacted]

The proposed finding is misleading to the extent it implies that the Open Offer includes these "template agreements." The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements Illumina is willing to provide customers. The Open Offer however, does not include the actual IVD agreement a customer would sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement would entail.

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony to support this "fact."

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding the FDA provision. [redacted]

[redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

1028.1 These options give customers access to all of Illumina's platforms that are currently available, as well as platforms that Illumina plans to develop in the future. (Goswami (Illumina) Tr. 3207–08.)

Response to Finding No. 1028.1

The proposed finding is misleading to the extent it implies that an Illumina IVD agreement is an "option" and customers are able to negotiate the terms of such an agreement.

[redacted]

[redacted]

Illumina customers testified to their minimal negotiating leverage with Illumina as Illumina is their sole supplier and there are no alternatives to switch to. For example, Singlera's Mr. Gao testified the Singlera has "[z]ero pretty much" negotiating leverage with Illumina. Mr. Gao continued "not only zero, in our heart we have a resentment kind of feel. Maybe Illumina will use this strategy to suppress us." (PX7042 (Gao (Singlera) IHT at 84-85). Additionally, [redacted]

The proposed finding is misleading to the extent it implies that the Open Offer includes the actual IVD agreement "options." The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements Illumina is willing to provide customers. The Open Offer however, does not include the actual IVD agreement a customer would sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement would entail.

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional

supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021))

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony to support this "fact."

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding the FDA provision. [redacted]

The proposed finding is misleading because it fails to mention how the IVD agreement provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

[redacted]

1028.2 The Open Offer lays out the summary terms for the different types of IVD agreements. (Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 28–40.) More detailed templates of the different agreements are also available to interested customers. (Goswami (Illumina) Tr. 3208.)

Response to Finding No. 1028.2

The proposed finding is vague because it fails to define or describe what the terms "summary terms," "more detailed" and "different agreements" mean. The proposed finding is vague because it fails to explain where these "more detailed templates" are located and how a customer would go about finding them. The proposed finding is also vague because it fails to explain what is included in these "more detailed templates."

The proposed finding is misleading to the extent it implies the Open Offer states that Exhibit B – IVD Test Kit Agreement Terms is only the "summary terms" and that "more detailed templates… are also available to interested customers." (PX0064 at 028 (Illumina Open Offer, Mar. 29, 2021)). It is unclear from the terms of the Open Offer how customers will know that there are "more detailed templates" available and who the customer must contact to receive such "templates."

The proposed finding is misleading to the extent it implies customers are able to negotiate the terms of an Illumina IVD agreement. [redacted]

[redacted]

Illumina customers testified to their minimal negotiating leverage with Illumina as Illumina is their sole supplier and there are no alternatives to switch to. For example, Singlera's Mr. Gao testified the Singlera has "[z]ero pretty much" negotiating leverage with Illumina. Mr. Gao continued "not only zero, in our heart we have a resentment kind of feel. Maybe Illumina will use this strategy to suppress us." (PX7042 (Gao (Singlera) IHT at 84-85). Additionally, [redacted]

The proposed finding is misleading to the extent it implies that the Open Offer includes the full terms of an Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer however, does not include the actual IVD agreement a customer would sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement would entail.

The proposed finding relies solely on the testimony of Illumina's Senior Vice President

of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony to support this "fact." Therefore, this Court should disregard the proposed finding.

> 1028.3 The terms in the Open Offer's template IVD agreements are standard in the industry and are generally accepted by companies like Thermo Fisher that serve multiple clients in the same industry. (Goswami (Illumina) Tr. 3210, 3212, 3215, 3228–29; *see* [redacted] Dr. Joydeep Goswami, Illumina's Chief Strategy and Corporate Development Officer, worked at Thermo Fisher for 16 years and led its clinical oncology and NGS division. (Goswami (Illumina) Tr. 3181.) Dr. Goswami confirmed that the Open Offer's IVD agreement terms reflect industry standards. (Goswami (Illumina) Tr. 3210, 3212, 3215, 3228–29.)

Response to Finding No. 1028.3

The proposed finding is vague because it fails to define or explain what "standard in the industry" and "industry standards" mean and what "industry" is being referred to. The proposed finding is vague because it fails to define or describe what the terms "generally accepted" and "same industry" mean.

[redacted]

[redacted]

The proposed finding is misleading to the extent it implies that Thermo's IVD agreements have the same monetary fees, in the tens of millions with revenue shares, as Illumina's IVD agreement include.

The proposed finding is misleading to the extent it implies that the Open Offer includes the full terms of an Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer however, does not include the actual IVD agreement a customer would sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement would entail. Therefore, this Court should disregard the proposed finding.

1029. A customer can develop an unlimited number of IVD test kits under the All-Platforms Agreement. (Goswami (Illumina) Tr. 3208–09; PX0064 (Illumina) at 28.) For the NextSeq Agreement and the NovaSeq Agreement, customers can develop up to 3 tests. (Goswami (Illumina) Tr. 3209; PX0064 (Illumina) at 28.)

Response to Finding No. 1029

The proposed finding is misleading to the extent it implies that the Open Offer includes the full terms of an Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer however, does not include the actual IVD agreement a customer would sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement would entail.

The proposed finding is misleading to the extent it implies that Illumina provides a customer the ability to develop IVD test kits at a low price. The IVD agreement rubric provided

in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). For example, if a customer wants to develop an "unlimited" amount of IVD test kits, the customer will have to pay a $25 million tech access fee, development milestone payments of $1 million per IVD test kit on the NextSeqDx platform, $5 million per IVD test kit on the NovaSeqDx platform, and an unknown dollar amount per IVD test kit on "future platforms," and a revenue share of 6% of net sales of the IVD test kits. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding.

1029.1 Illumina determined the number of tests that customers could develop on each platform based on what Illumina had agreed to with previous partners. (Goswami (Illumina) Tr. 3209.)

Response to Finding No. 1029.1

The proposed finding is vague because it is unclear whether Respondents are referring to the "unlimited" or three test kits only IVD agreement options. The proposed finding is vague because it fails to define who these "previous partners" are and whether they are clinical customers and specifically cancer detection partners.

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony to support this "fact." Therefore, this Court should disregard the proposed finding.

1030. All IVD agreements under the Open Offer extend to all jurisdictions worldwide where Illumina has obtained regulatory clearance for the instruments. (Goswami (Illumina) Tr. 3209; PX0064 (Illumina) at 28.)

Response to Finding No. 1030

Complaint Counsel acknowledges that the following language is included in Illumina's Open Offer, "Territory[:] Worldwide, in jurisdictions where the applicable IVD Hardware has

regulatory approval." (PX0064 at 028 Illumina Open Offer, Mar. 29, 2021)).

The proposed finding is misleading to the extent it implies that the this territory language will be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer however, does not include the actual IVD agreement a customer would sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement would entail.

The proposed finding is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore,

this Court should disregard the proposed finding.

1031. The All-Platforms Agreement has a 15–year term. (Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 29.) The NextSeq Agreement and the NovaSeq Agreement have 10–year terms. (Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 29.) Developers may also commercialize their tests beyond the stated term lengths. (Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 29.)

Response to Finding No. 1031

The proposed finding is vague because it is unclear what "developers may also commercialize their tests beyond the stated term lengths." The proposed finding is misleading because it fails to acknowledge an important limitation on a customer's ability to "commercialize their tests beyond the states term length." Specifically, the Open Offer's IVD agreement rubric states "Continued Commercialization: After expiration of the Term, Customer may continue commercializing IVD Test Kits that were launched before expiration of the Term *for so long as* Illumina is still commercializing the applicable Sequencing Consumables and servicing and supporting the applicable IVD Hardware in the applicable Territory." (PX0064 at 029 (Illumina Open Offer Agreement, Mar. 29, 2021) (emphasis added)). Thus, a customer may be limited from commercializing its IVD test kit if Illumina is no longer "commercializing the applicable Seqeuncing Consumables and servicing and support the applicable IVD Hardware in the applicable Territory." It is unclear what amount to an "applicable" consumable or IVD Hardware means or who gets to make this determination. Additionally, it is unclear what amount to "servicing" or "support" and who gets to make this determination.

The proposed finding is misleading to the extent it implies that the term length referred to here is guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the

final terms of an IVD agreement will entail. Therefore, this Court should disregard the proposed finding.

> 1031.1 Specifically, the Open Offer requires that, for the All-Platforms Agreement, the "Term of Agreement (during which time Customer could sell IVD Test Kits) would be 15 years from the date the Transaction closes. Customer could enter into new IVD Plans for IVD Test Kit development during the first 10 years (the 'Development Term')". (PX0064 (Illumina) at 29.) For the NextSeq Agreement, the Open Offer requires that the term is "10 years from the date the Transaction closes". (PX0064 (Illumina) at 29.) And for the NovaSeq Agreement, the Open Offer requires that the term is "10 years from the later of (i) the date the Transaction closes or (ii) the date NovaSeqDx is listed with FDA in the U.S. pursuant to applicable law". (PX0064 (Illumina) at 29.)

Response to Finding No. 1031.1

The proposed finding is misleading to the extent it implies that the term length referred to here is guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail. Therefore, this Court should disregard the proposed finding.

> 1031.2 The Open Offer also requires that "[a]fter expiration of the Term, Customer may continue commercializing IVD Test Kits that were launched before expiration of the Term for so long as Illumina is still commercializing the applicable Sequencing Consumables and servicing and supporting" the applicable instruments in the applicable territory. (PX0064 (Illumina) at 29.)

Response to Finding No. 1031.2

The proposed finding is vague because it fails to define or describe what the phrases "servicing and supporting," "applicable instruments," "applicable territory" mean. The proposed finding is misleading because it fails to acknowledge an important limitation on a customer's ability to "commercialize their tests beyond the states term length." Specifically, the Open

Offer's IVD agreement rubric states "Continued Commercialization: After expiration of the Term, Customer may continue commercializing IVD Test Kits that were launched before expiration of the Term *for so long as* Illumina is still commercializing the applicable Sequencing Consumables and servicing and supporting the applicable IVD Hardware in the applicable Territory." (PX0064 at 029 (Illumina Open Offer Agreement, Mar. 29, 2021) (emphasis added)). Thus, a customer may be limited from commercializing its IVD test kit if Illumina is no longer "commercializing the applicable Sequencing Consumables and servicing and support the applicable IVD Hardware in the applicable Territory." It is unclear what amount to an "applicable" consumable or IVD Hardware means or who gets to make this determination. Additionally, it is unclear what amount to "servicing" or "support" and who gets to make this determination.

The proposed finding is misleading to the extent it implies that the term lengths referred to here are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail. Therefore, this Court should disregard the proposed finding.

> 1031.3 Illumina selected the 10 and 15–year terms based on industry standards and the goal of giving customers enough time to develop kits on the relevant platforms. (Goswami (Illumina) Tr. 3210.)

Response to Finding No. 1031.3

The proposed finding is vague because it fails to define or explain what "industry standards" mean and what "industry" Respondents are referring to.

The proposed finding relies solely on the testimony of Illumina's Senior Vice President

of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony or other "industry" participates to support what the "industry standard" is and what Illumina's goal is.

The proposed finding is misleading to the extent it implies that the term lengths referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail. Therefore, this Court should disregard the proposed finding.

1032. The Open Offer's IVD agreement templates include 3 types of financial considerations: (1) a technology access fee, paid upfront; (2) milestones due when a test developer progresses towards development of a kit; and (3) a 6% revenue share due only after the developer launches the kit. (PX0064 (Illumina) at 29–30.)

Response to Finding No. 1032

The proposed finding is misleading to the extent it implies that the financial consideration referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail.

The proposed finding is misleading to the extent it implies that customer monetary payments under the Open Offer's IVD agreement rubrics are insignificant amounts. Under the IVD agreement rubric provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030

(Illumina Open Offer, Mar. 29, 2021)). For example, if a customer wants to develop an "unlimited" amount of IVD test kits, the customer will have to pay a $25 million tech access fee, development milestone payments of $1 million per IVD test kit on the NextSeqDx platform, $5 million per IVD test kit on the NovaSeqDx platform, and an unknown dollar amount per IVD test kit on "future platforms," and a revenue share of 6% of net sales of the IVD test kits. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

Therefore, this Court should disregard the proposed finding.

1032.1 The financial terms of the agreements are standard in the industry. (Goswami (Illumina) Tr. 3212; [redacted] PX7097 (Felton (Thermo Fisher) Dep. at 127–29).)

Response to Finding No. 1032.1

The proposed finding is vague because it fails to define or explain what "standard in the industry" and "industry standards" mean and what "industry" is being referred to. The proposed finding is vague because it fails to define or describe what the terms "generally accepted" and "same industry" mean.

The proposed finding is misleading to the extent it implies Thermo Fisher testified that Illumina's Open Offer "IVD agreements are standard in the industry." [redacted]

[redacted]

The proposed finding is misleading to the extent it implies that Thermo's IVD agreements have the same monetary fees, in the tens of millions with revenue shares, as Illumina's IVD agreement include.

The proposed finding is misleading to the extent it implies that the financial consideration referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail. Therefore, this Court should disregard the proposed finding.

> 1032.2 The financial terms are split into 3 components to ensure fairness and to distribute the fees over a period of time based on the success and commercial milestones of the developer. (Goswami (Illumina) Tr. 3213.)

Response to Finding No. 1032.2

The proposed finding is vague because it fails to define or describe what "fairness" means.

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any

customer testimony or documentary evidence to support the claim that Illumina's IVD agreement financial terms are split into three components to "ensure fairness". Additionally, Respondents fail to cite to any customer testimony to support their statement about distributing the fees over a period of time that is "based on the success and commercial milestones of the developer."

The proposed finding is misleading to the extent it implies that the financial consideration referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail.

The proposed finding is misleading to the extent it implies that customer monetary payments under the Open Offer's IVD agreement rubrics are insignificant amounts. Under the IVD agreement rubric provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). For example, if a customer wants to develop an "unlimited" amount of IVD test kits, the customer will have to pay a $25 million tech access fee, development milestone payments of $1 million per IVD test kit on the NextSeqDx platform, $5 million per IVD test kit on the NovaSeqDx platform, and an unknown dollar amount per IVD test kit on "future platforms," and a revenue share of 6% of net sales of the IVD test kits. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

Therefore, this Court should disregard the proposed finding.

1032.3 For the All-Platforms Agreement, the technology access fee is $25 million. (PX0064 (Illumina) at 29.) The technology access fee for the NextSeq

> Agreement is $3 million and the technology access fee for the NovaSeq Agreement is $15 million. (PX0064 (Illumina) at 29.) The technology access fees were selected based on recovering Illumina's upfront investment in the platforms and staying consistent with standard market. (Leite (Illumina/InterVenn) Tr. 2162–63; Goswami (Illumina) Tr. 3213–14.)

Response to Finding No. 1032.3

The proposed finding is vague because it fails to define or explain what the phrases "recovering Illumina's upfront investment" and "standard market" mean. The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and Illumina's former Vice President of Business Development, Mr. Leite, and fails to cite to any customer testimony or documentary evidence to support the claim "the technology access fees were selected based on recovering Illumina's upfront investment in the platforms and staying consistent with standard market."

The proposed finding is misleading to the extent it implies that the financial consideration referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail.

The proposed finding is misleading to the extent it implies that customer monetary payments under the Open Offer's IVD agreement rubrics are insignificant amounts. Under the IVD agreement rubric provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). For example, if a customer wants to develop an "unlimited" amount of IVD test kits, the customer will have to pay a $25 million tech access fee, development milestone payments of $1 million per IVD test kit on the NextSeqDx platform, $5

million per IVD test kit on the NovaSeqDx platform, and an unknown dollar amount per IVD test kit on "future platforms," and a revenue share of 6% of net sales of the IVD test kits. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

The proposed finding is misleading to the extent it implies that Illumina selected fee amounts based on "recovering Illumina's upfront investment in the platforms and staying consistent with standard market." [redacted]

1032.4 The 6% revenue share was chosen based on a midpoint of what is common in the life sciences and diagnostics industry. (Goswami (Illumina) Tr. 3215.)

Response to Finding No. 1032.4

The proposed finding is vague because it fails to define or explain what the phrases "midpoint," "common," "life sciences" and "diagnostic industry" mean. The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony, industry

participant testimony, or documentary evidence to support the claim "the 6% revenue share was chosen based on a midpoint of what is common in the life sciences and diagnostics industry."

The proposed finding is misleading to the extent it implies that the financial consideration referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail.

The proposed finding is misleading to the extent it implies that customer monetary payments under the Open Offer's IVD agreement rubrics are insignificant amounts. Under the IVD agreement rubric provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). For example, if a customer wants to develop an "unlimited" amount of IVD test kits, the customer will have to pay a $25 million tech access fee, development milestone payments of $1 million per IVD test kit on the NextSeqDx platform, $5 million per IVD test kit on the NovaSeqDx platform, and an unknown dollar amount per IVD test kit on "future platforms," and a revenue share of 6% of net sales of the IVD test kits. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

The proposed finding is misleading to the extent it implies that Illumina selected the 6% revenue share amount based on "a midpoint of what is common in the life sciences and diagnostics industry." [redacted]

[redacted]

1032.5 The milestone payments were determined based on securing a return on Illumina's initial investment, as well as on previous successful negotiations with partners. (Goswami (Illumina) Tr. 3215–16.)

Response to Finding No. 1032.5

The proposed finding is vague because it fails to define or explain what the phrases "securing a return," "Illumina's initial investment," "previous successful negotiations" and "partners" mean. It is unclear who these "partners" Respondents refer to include.

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony or documentary evidence to support the claim "The milestone payments were determined based on securing a return on Illumina's initial investment, as well as on previous successful negotiations with partners."

The proposed finding is misleading to the extent it implies that the financial consideration referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a

customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail.

The proposed finding is misleading to the extent it implies that customer monetary payments under the Open Offer's IVD agreement rubrics are insignificant amounts. Under the IVD agreement rubric provided in the Open Offer requires customers to pay tens of millions of dollars and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). For example, if a customer wants to develop an "unlimited" amount of IVD test kits, the customer will have to pay a $25 million tech access fee, development milestone payments of $1 million per IVD test kit on the NextSeqDx platform, $5 million per IVD test kit on the NovaSeqDx platform, and an unknown dollar amount per IVD test kit on "future platforms," and a revenue share of 6% of net sales of the IVD test kits. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

The proposed finding is misleading to the extent it implies that Illumina selected the milestone payments amounts "based on securing a return on Illumina's initial investment, as well as on previous successful negotiations with partners." [redacted]

[redacted]

1032.6 Developers who develop competing tests to those being developed by Illumina are not charged more than noncompetitors under the Open Offer. (Goswami (Illumina) Tr. 3216.)

Response to Finding No. 1032.6

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony or documentary evidence to support the "fact."

The proposed finding is misleading because the fact that all customers may be paying the same for an IVD agreement does not prove that Illumina did not select these monetary terms to offset their loss from competitive tests, but at now applying them to all customers.

[redacted] Thus, the fact that all customers are subject to the same high monetary fees does not mean Illumina selected these fees for any other reason than offsetting their loss from

competitor tests. Therefore, this Court should disregard the proposed finding.

1033. The Open Offer provides for interested customers to submit proposed IVD plans to Illumina, which Illumina may not unreasonably reject. (PX0064 (Illumina) at 34–35.)

Response to Finding No. 1033

The proposed finding is vague because "IVD plans" is undefined. The Open Offer states that a "IVD Plan" is a "development plan" which sets out "the parties' specific development obligations and timelines with respect to each IVD Test Kit." (PX0064 at 034 (Illumina Open Offer, Mar. 29, 2021)). It is unclear what IVD Plans are used for or why an IVD Plan may be rejected.

The proposed finding is vague because it is unclear what amounts to a reasonable rejection under the Open Offer. Additionally, who gets to decide whether a rejection is reasonable and what is a customer's ability to challenge this if the customer does not agree with the reasonableness determination. Therefore, this Court should disregard the proposed finding.

> 1033.1 The Open Offer requires that "[e]ach IVD Test Kit, and the parties' specific development obligations and timelines with respect to each IVD Test Kit, would be described in a development plan to be negotiated in good faith (each, an 'IVD Plan'.) Customer would propose potential IVD Plans. Illumina may not unreasonably reject any proposed IVD Plan." (PX0064 (Illumina) at 34–35.)

Response to Finding No. 1033.1

The proposed finding is vague because it is unclear what IVD Plans are used for or why an IVD Plan may be rejected.

The proposed finding is vague because it is unclear what amounts to a reasonable rejection under the Open Offer. Additionally, who gets to decide whether a rejection is reasonable and what is a customer's ability to challenge this if the customer does not agree with the reasonableness determination.

> 1033.2 Illumina provides two categories of information to customers during the IVD agreement process: (1) an overview of countries where Illumina has regulatory

approval and the number of instruments in each region or country and (2) authorization to access the device master file when the customer requires it for FDA approval. (Goswami (Illumina) Tr. 3223–24.)

Response to Finding No. 1033.2

The proposed finding relies solely on the testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony or documentary evidence to support what information is provided to customers.

The proposed finding is vague because it fails to define or describe what "the device master file" is. Therefore, this Court should disregard the proposed finding.

1033.3 In the IVD agreement process, Illumina receives from developers only basic information about the kind of test the developer is creating and the developer's development plans. (Goswami (Illumina) Tr. 3226–27.) This information is to help Illumina plan for certain commitments and obligations that it has to the developer. (Goswami (Illumina) Tr. 3227.)

Response to Finding No. 1033.3

The proposed finding is misleading to the extent it implies that "in the IVD agreement process, Illumina receives from developers only basic information about the kind of test the developer is creating and the developer's development plans." [redacted] Therefore, this Court should disregard the proposed finding.

1033.4 Illumina does not receive access to proprietary information from developers through the IVD agreement process. (Goswami (Illumina) Tr. 3227.)

Response to Finding No. 1033.4

The proposed finding relies solely on the testimony of Illumina's Senior Vice President

of Corporate Development and Strategic Planning, Mr. Goswami, and fails to cite to any customer testimony or documentary evidence to support the claim that customers do not provide proprietary information to Illumina.

The proposed finding is misleading to the extent it implies that "Illumina does not receive access to proprietary information from developers through the IVD agreement process."

Therefore, this Court should disregard the proposed finding.

1034.

Response to Finding No. 1034

[redacted]

1034.1 [redacted]

Response to Finding No. 1034.1

[redacted]

[redacted]

1034.2 [redacted]

Response to Finding No. 1034.2

[redacted]

1034.3 The terms of IVD agreements that Illumina has entered into were not intended to raise the prices of kitted oncology assays, nor to diminish innovation in the area of kitted oncology assays. (Goswami (Illumina) Tr. 3217–18.) Providing an infrastructure on which developers can create tests allows them to develop more quickly and to lower costs for development. (Goswami (Illumina) Tr. 3217.) These IVD agreements spur innovation because many customers would not have been able to consider IVD tests without access to an infrastructure like Illumina's. (Goswami (Illumina) Tr. 3217–18; *see also* Leite (Illumina/InterVenn) Tr. at 2181–82.)

Response to Finding No. 1034.3

The proposed finding is vague because it fails to define or explain what the phrases "were not intended" and "infrastructure like Illumina's" mean.

[redacted]

1034.4 Illumina is holding GRAIL separate and would be happy to enter into an IVD agreement with GRAIL, but GRAIL has not indicated any intention to do so yet. [redacted] 3273.)

Response to Finding No. 1034.4

[redacted]

[redacted]

[redacted]

1034.5 [redacted]

Response to Finding No. 1034.5

[redacted]

1035. The Open Offer provision on IVD agreements and FDA documentation addresses the potential foreclosure concerns that have been raised because they prevent Illumina from withholding support as MCED test developers seek FDA approval. (RX6002 (Guerin-Calvert Trial Dep. at 74).)

Response to Finding No. 1035

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer subject to the Open Offer to support Respondents' proposed "fact."

The proposed finding is vague because it fails to define or describe what "potential foreclosure concerns" it is referring to. The proposed finding is also vague because it is unclear

how the Open Offer's IVD agreement "prevent[s] Illumina from withholding support as MCED test developers seek FDA approval.

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding Illumina's assistance of customer going through FDA approval.

[redacted]

1035.1 By using standardized agreements, the provision ensures that customers know in advance what the terms of such an agreement will be. (RX6002 (Guerin-Calvert Trial Dep. at 74–75).)

Response to Finding No. 1035.1

The proposed finding is vague because it fails to define or describe what "standardized agreements," "the provision," and "agreement" the Respondents are referring to.

The proposed finding is misleading to the extent it implies that standardized agreements resolve customer concerns regarding the Open Offer. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1035.2 [redacted]

Response to Finding No. 1035.2

[redacted]

[redacted]

1035.3 The IVD agreement and FDA documentation provision specifically guarantees that Illumina will provide equal or greater assistance to MCED test developers with respect to FDA approval than it did premerger. (RX6002 (Guerin-Calvert Trial Dep. at 75).)

Response to Finding No. 1035.3

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry or any customer subject to the Open Offer to support Respondents' proposed "fact."

The proposed finding is vague because it fails to point to which part of the FDA provision in the Open Offer "specifically guarantees that Illumina will provide equal or greater assistance to MCED test developers with respect to FDA approval than it did premerger." The Open Offer makes no such "guarantee." (PX0064 (Illumina) at 008 (Illumina Open Offer, Mar. 29, 2021)). Additionally, the proposed finding is vague because it fails to define or explain what "equal or greater assistance" means. It is unclear who gets to decide whether a customer has been provided "equal or greater assistance" and who this "equal or greater assistance" is based off of.

The term "guarantee" is misleading to the extent it implies that Illumina cannot breach

the terms of the Open Offer. As [redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

Ultimately, as [redacted]

6. **Intellectual Property**

1036. Customers who sign the Open Offer receive a right under Illumina's core intellectual property to use the relevant products. (deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

Response to Finding No. 1036

The proposed finding is vague because it fails to define or describe what "relevant products" includes. Additionally, nowhere in the intellectual property provision of the Open Offer uses the term "relevant product." (PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)). The proposed finding is vague because it fails to define or describe what "core intellectual property" means even though it is a define term in the Open Offer. (PX0064 at 033 (Illumina Open Offer agreement, Mar. 29, 2021)).

The proposed finding is misleading to the extent it implies that a right to Illumina's core intellectual property resolves customers concerns re intellectual property. Customers are concerned that Illumina may wield its application-specific IP, which is specifically carved out of the Open Offer terms, to disadvantage Grail's rivals. [redacted] Guardant's Mr. Getty has concerns about Illumina and Grails combined intellectual property portfolio post-acquisition. (PX7040 (Getty (Guardant) IHT at 192-93) (stating that "intellectual property is a very important component" and "it forms a moat for others to have – to have to penetrate in

order to, you know, be a formidable competitor. And so, you know, the intersection of the IP associated with a company who owns all the underlying technology and then, you know, potentially layering on additional patents on top of that, you know, it creates a rather challenging dynamic for other companies to potentially develop competing modalities that leverage that underlying technology because there's an intersection there")). Mr. Getty testified that he anticipates that the Illumina-Grail intellectual property portfolio will impact Guardant's decisions on innovating going forward. (PX7040 (Getty (Guardant) IHT at 193) (adding that "in large part everyone is dependent on Illumina," and that if Illumina were to "suggest that there is some, you know, infringement ongoing," that "[i]t just may stop you in your track to say, Wow, we can't afford to fight with them")). [redacted]

The proposed finding is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted]

[redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1036.1 "'Intellectual Property Right(s)' means all rights in patent, copyrights (including rights in computer software), trade secrets, know-how, trademark, service mark and trade dress rights and other industrial or intellectual property rights under the laws of any jurisdiction, whether registered or not and including all applications therefor and registrations thereto." (PX0064 (Illumina) at 4.)

Response to Finding No. 1036.1

Complaint Counsel acknowledges that the Open Offer contains the quoted language. However, it is misleading to assume that Illumina will abide by the terms of its Open Offer. As

[redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

The proposed finding is misleading to the extent it carves out protection for application specific intellectual property. Customers testified to the importance of application-specific IP and how Illumina can wield its application-specific IP to disadvantage Grail rivals. Illumina's Open Offer does not provide customers a right or license to any application-specific IP, and in fact carves application-specific IP out of the Open Offer's IP protections. (*See* PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)). [redacted]

[redacted] is made even more real by the fact that Illumina's arbitration provision specifically carves out intellectual property disputes allowing Illumina to entangle customers in years long legal battles even if no IP infringement is ever proven. (PX0064 at 10 (Illumina Open Offer agreement, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding.

> 1036.2 "'Illumina Intellectual Property Rights' means all Intellectual Property Rights owned or controlled by Illumina or Affiliates of Illumina during the Term of this Agreement. Application Specific IP and Core IP are separate, non-overlapping, subsets within the Illumina Intellectual Property Rights." (PX0064 (Illumina) at 4.)

Response to Finding No. 1036.2

Complaint Counsel acknowledges that the Open Offer contains the quoted language. However, it is misleading to assume that Illumina will abide by the terms of its Open Offer. As [redacted]

[redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1036.3 "'Core IP' means Illumina Intellectual Property Rights that pertain to or cover aspects or features of any Supplied Product (or use thereof), or software embedded in or installed on Illumina hardware (or use thereof), or software that Illumina hardware is designed to communicate or interact with (or use thereof), that are common to such Supplied Product in all applications and all fields of use." (PX0064 (Illumina) at 3.)

Response to Finding No. 1036.3

Complaint Counsel acknowledges that the Open Offer contains the quoted language. However, it is misleading to assume that Illumina will abide by the terms of its Open Offer. As [redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1036.4 The Open Offer requires that "Customer's purchase of Supplied Products under this Supply Agreement confers upon Customer the non-exclusive, non-transferable, personal, non-sublicensable right solely under Illumina's Core IP to use the Supplied Products, only with Illumina hardware and software, and only in Customer facilities." (PX0064 (Illumina) at 9.)

Response to Finding No. 1036.4

Complaint Counsel acknowledges that the Open Offer contains the quoted language. However, the term "requires" is misleading to assume that Illumina will abide by the terms of its Open Offer. As [redacted]

Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted]

[redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

> 1036.5 The Open Offer's provision on the right to use the Supplied Products under Illumina's Core IP addresses the potential foreclosure concerns that have been raised by ensuring that there will be no concern or confusion about whether these Core IP rights will be provided to customers in the future. (RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

Response to Finding No. 1036.5

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer subject to the Open Offer to support Respondents' proposed "fact."

The proposed finding is vague because it fails to define or describe what "potential foreclosure concerns" it is referring to.

The proposed finding is misleading to the extent it implies the Open Offer resolves customer concerns regarding Illumina's ability and incentive to wield its intellectual property in order to disadvantage Grail's rivals. Freenome requested such a license because it was concerned that Illumina may wield its application-specific IP, which is specifically carved out of the Open Offer terms, to disadvantage them and Grail's rivals. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Customer concerns regarding Illumina's incentive and ability to disadvantage Grail's rivals through the use of intellectual property litigation has become even more real with Illumina suing Guardant. Shortly after the Part 3 hearing in the Illumina-Grail matter, where Guardant put forward two witnesses to testify at trial on behalf of the Government, Illumina sued Guardant in federal court, alleging intellectual property violations against Guardant's founders from when they were Illumina employees over nine years ago and that Illumina allegedly learned about three years ago. (*See* Complaint, Illumina, Inc. v. Guardant Health, Inc., et. al., No. 1:22-cv-00334 (D. Del. Mar. 17, 2022)). Therefore, this Court should disregard the proposed finding.

1037. Under the Open Offer, Illumina commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

Response to Finding No. 1037

The proposed finding is misleading and unclear because the use of "solely on the basis of a claim of infringement of Illumina's intellectual property" under this term of the Open Offer

means Illumina could cease shipments of products if a claim of IP infringement is coupled with another claim. It is unclear to what this other claim needs to be or to what extent it must be proven.

The proposed finding is misleading to the extent it implies Illumina cannot breach the terms of the Open Offer. As [redacted]

1037.1 The Open Offer requires that "[i]n no event will Illumina have the right to cease shipping of the Supplied Product solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina." (PX0064 (Illumina) at 9.)

Response to Finding No. 1037.1

The proposed finding is misleading and unclear because the use of "solely on the basis of a claim of infringement of Illumina's intellectual property" under this term of the Open Offer

means Illumina could cease shipments of products if a claim of IP infringement is coupled with another claim. It is unclear to what this other claim needs to be or to what extent it must be proven.

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. [redacted]

1037.2 This provision applies even if Illumina has a legitimate claim of infringement. (RX6002 (Guerin-Calvert Trial Dep. at 78).) [redacted]

Response to Finding No. 1037.2

[redacted]

[redacted]

1037.3 This provision effectively addresses the foreclosure concern that Illumina could disrupt supply to GRAIL rivals. (*See* RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

Response to Finding No. 1037.3

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). The Court should disregard this evidence.

The proposed finding is vague and misleading. The proposed finding is vague because the term "effectively addresses," "foreclosure concern," and "disrupt supply" are unclear and undefined. In addition, the finding purports to speak to all foreclosure concerns but relies solely on the self-serving testimony of Respondents' paid expert, with no corroboration from Illumina's customers.

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding supply disruption. [redacted]

[redacted]

7. Firewalls and Protection of Confidential Information

1038. The Open Offer requires Illumina not to share any customer confidential information with GRAIL or its subsidiaries or employees, or with Illumina employees who work with GRAIL. (Rabinowitz (Natera) Tr. 425; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Response to Finding No. 1038

The proposed finding is misleading because it incorrectly cites to Dr. Rabinowitz's testimony. Dr. Rabinowitz did not testify that the Open Offer "requires Illumina not to share any customer confidential information with GRAIL or its subsidiaries or employees, or with Illumina employees who work with GRAIL." [redacted] Respondents pick and choose the snippets of Dr. Rabinowitz testimony that best fit their narrative and in the process misconstrue what Dr. Rabinowitz testified to.

The proposed finding is vague because it fails to define or describe what constitutes "confidential information." Additionally, nowhere in the Open Offer is the term "confidential information" define. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021)). Even Illumina executive and Open Offer signatory testified that the Open Offer does not define what constitutes "confidential information." (Berry (Illumina) Tr. 716-18).

[redacted]

[redacted]

[redacted]

1038.1 The Open Offer requires that "[t]o the extent that Illumina may have access to confidential information ('Confidential Information') of Customer in connection with this Supply Agreement or the provision of Supplied Products by Illumina to Customer, Illumina shall in no event share such Confidential Information of Customer with GRAIL or any subsidiary of GRAIL, or any employees who work within GRAIL." (PX0064 (Illumina) at 9.)

Response to Finding No. 1038.1

The proposed finding is vague because it fails to define or describe what constitutes "confidential information." Additionally, nowhere in the Open Offer is the term "confidential information" define. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021)). Even Illumina executive and Open Offer signatory testified that the Open Offer does not define what constitutes "confidential information." (Berry (Illumina) Tr. 716-18).

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. **As** [redacted]

The proposed finding is also misleading to the extent it implies that Illumina can effectively prevent leaks between Illumina and GRAIL. [redacted]

[redacted]

The proposed finding is misleading to the extent it implies customers do not have concerns regarding the Open Offer's confidentiality provision. [redacted]

[redacted]

Ultimately, as Guardant's Mr. Getty testified with respect to Guardant's concerns about its confidential information being shared between Illumina and Grail, "Illumina has an incentive to share that information with GRAIL." (PX7105 (Getty (Guardant) Dep. at 100)). [redacted]

1039. Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (Rabinowitz (Natera) Tr. 425; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; PX7085 (Harada (Exact/Thrive) Dep. at 113–14).)

Response to Finding No. 1039

The proposed finding is misleading because it incorrectly cites to Dr. Rabinowitz's testimony. Dr. Rabinowitz did not testify that under the Open Offer "Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL." [redacted] Respondents pick and choose the snippets of Dr. Rabinowitz testimony that best fit their narrative and in the process misconstrue what Dr. Rabinowitz testified to.

[redacted]

[redacted]

The proposed finding is vague because it fails to define or describe what constitutes "confidential information." Additionally, nowhere in the Open Offer is the term "confidential information" define. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021)). Even Illumina executive and Open Offer signatory testified that the Open Offer does not define what constitutes "confidential information." (Berry (Illumina) Tr. 716-18).

[redacted]

[redacted]

[redacted]

1039.1 The Open Offer requires that "Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise." (PX0064 (Illumina) at 9–10.)

Response to Finding No. 1039.1

[redacted]

[redacted]

[redacted]

[redacted]

1039.2 The firewall provision was added to assure customers that Illumina will not allow GRAIL personnel or Illumina personnel who have interactions with GRAIL to access customer confidential information. (Goswami (Illumina) Tr. 3231.)

Response to Finding No. 1039.2

This proposed finding is misleading because it purports to speak to customer assurances but relies solely on the self-serving testimony of an Illumina executive without any corroboration from Illumina's customers. The proposed finding is also misleading to the extent it implies that Illumina can effectively prevent leaks between Illumina and GRAIL. [redacted]

[redacted]

1039.3 The firewall would still be able to protect information if employees moved from Illumina to GRAIL or from GRAIL to Illumina because Illumina clearly outlines what counts as confidential information and what the employees' obligations are under their confidentiality agreements. (Goswami (Illumina) Tr. 3232.)

Response to Finding No. 1039.3

The proposed finding is vague and misleading because it fails to explain how "Illumina clearly outlines what counts as confidential information." The proposed finding is vague because it fails to define or describe what constitutes "confidential information." Additionally, nowhere in the Open Offer is the term "confidential information" define. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021)). Even Illumina executive and Open Offer signatory testified that the Open Offer does not define what constitutes "confidential information." (Berry (Illumina) Tr. 716-18).

The proposed finding is vague because it fails to explain or describe what these "employee[] obligations" are. The proposed finding is unsupported because Respondents fail to cite to any of the "confidentiality agreements" where Illumina has "clearly outline[d] what counts as confidential information and what the employees' obligations are…"

This proposed finding is misleading because it relies solely on the self-serving testimony of an Illumina executive. The proposed finding is also misleading to the extent it implies that Illumina can effectively prevent leaks between Illumina and GRAIL. [redacted]

[redacted]

1039.4 If someone at Illumina shares confidential information of a test developer with someone at GRAIL, there are codified disciplinary procedures in place, up to termination of the employee. (Goswami (Illumina) Tr. 3232–33.)

Response to Finding No. 1039.4

This proposed finding is vague and misleading. The proposed finding is vague because "codified disciplinary procedures" is undefined.

This proposed finding is misleading because it relies solely on the self-serving testimony of an Illumina executive. The proposed finding is also misleading to the extent it implies that Illumina can effectively prevent leaks between Illumina and GRAIL. [redacted]

[redacted]

[redacted]

1039.5 If Illumina becomes aware of a breach of confidentiality of any kind, it is obligated to notify the other party of the breach. (Goswami (Illumina) Tr. 3233; RX3935 (Illumina) at 3.) Illumina will also conduct a biannual audit to identify any breaches it could have missed. (Goswami (Illumina) Tr. 3233; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

Response to Finding No. 1039.5

The proposed finding is misleading to the extent it implies that customers will be able to monitor and enforce obligation to notify. MCED customers testified that they have no way of knowing when confidential information is shared between Illumina and another customer, including Grail. When asked what specifically was flawed about Illumina's firewall provision, Guardant's Mr. Getty testified: "There's no enforceability of it. And with – if it was breached, how would [Guardant] know, right." (PX7040 (Getty (Guardant) IHT at 189)). [redacted]

[redacted]

The term "obligated" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

To the extent this finding purports to interpret the Open Offer, it should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

1039.6 The firewall provision in the Open Offer will not impede Illumina from realizing efficiencies from the merger. (Aravanis (Illumina) Tr. 1946, 1948, 1959.)

Response to Finding No. 1039.6

This proposed finding is vague because the term "realizing efficiencies" is unclear and undefined.

The proposed finding is unsupported and conclusory because it does not provide any explanation for why "the firewall provision in the Open Offer will not impede Illumina from realizing efficiencies from the merger." Therefore, this Court should disregard the proposed finding.

> 1039.7 Implementing the firewall envisioned by the Open Offer would mitigate customer concerns about the potential for sharing sensitive information between Illumina and GRAIL. (PX7077 (Chahine (Helio) Dep. at 123–24.)

Response to Finding No. 1039.7

The proposed finding is misleading to the extent it implies that the firewall provision resolves customers concerns regarding confidential information. [redacted]

[redacted]

[redacted]

1040. Illumina protects the confidentiality of information it receives from developers in the IVD agreement process in multiple ways. (Goswami (Illumina) Tr. 3227–28.)

Response to Finding No. 1040

The proposed finding is vague because it fails to define or describe the "multiple ways" Illumina "protects the confidentiality of information it receives" in IVD agreements. Additionally, the proposed finding is vague because it fails to describe what information Illumina is "protecting."

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, and does not cite to any documents or written policy procedures which to support Respondents' proposed "fact."

The proposed finding is misleading to the extent it implies that Illumina protects confidentiality at all times. Evidence shows that a firewall is difficult for Illumina to maintain.

[redacted]

[redacted] Guardant's Mr. Getty testified that Illumina's firewall provision does "not at all" alleviate Guardant's concerns about the sharing of competitively sensitive information with Illumina. (PX7040 (Getty (Guardant) IHT at 188)). This is because "individuals on [Illumina's] executive team have traded back and forth already. . . . There are individuals – you know, Illumina was an early investor in Grail, and there are individuals who are on the executive team at Illumina who hold large stakes in Grail." (PX7040 (Getty (Guardant) IHT at 188-89)). [redacted]

When asked whether the firewall provision in the Open Offer alleviates concerns about sharing of competitively sensitive information, Mr. Getty testified, "No, it does not. I – you know, I think the notion of a firewall invokes something that is impossible to enforce." (PX7105 (Getty (Guardant) Dep. at 102)). [redacted] Therefore, this Court should disregard the proposed finding.

1040.1 First, Illumina sets up a confidentiality agreement with all of its partners early on in the process. (Goswami (Illumina) Tr. 3228.)

Response to Finding No. 1040.1

The proposed finding is vague because it fails to define or describe who these "partners"

are and what "early on in the process" means. The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, and does not cite to any documents, written policy or procedures, or customer testimony to support Respondents' proposed "fact."

The proposed finding is misleading to the extent it implies Illumina has confidentiality agreements with all its customers. Therefore, this Court should disregard the proposed finding.

> 1040.2 Second, Illumina trains its staff and requires them to sign confidentiality agreements when they are hired. (Goswami (Illumina) Tr. 3228.)

Response to Finding No. 1040.2

The proposed finding is vague because it fails to define or describe how Illumina "trains its staff." The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, and does not cite to any specific documents or written policies and procedures to support Respondents' proposed "fact."

The proposed finding is misleading to the extent it implies Illumina employees do not move to other companies, specifically Grail, taking with them the confidential information they learned while employed at Illumina. [redacted]

> 1040.3 Third, Illumina separates teams that work with customers who might have similar products. (Goswami (Illumina) Tr. 3228.)

Response to Finding No. 1040.3

The proposed finding is vague because it fails to define or describe what "similar products" means. The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, and does not cite to any specific documents or written policies and procedures to support Respondents' proposed "fact."

The proposed finding is misleading to the extent it implies that the Illumina employee which oversees these "separate teams" does not have information about customers who have "similar products." Illumina's Senior Vice President and General Manager of the Americas, Ms. Nicole Berry, testified that she is "responsible for the customer-facing functions in the United States, Canada and Latin America." (PX7063 (Berry (Illumina) IHT at 14)). "Customer-facing functions" means Illumina's "sales teams and it's… service and support teams…" (PX7063 (Berry (Illumina) IHT at 14)). In Ms. Berry's role she can simply ask her "business analytics folds to run [her] a report" on what products customers are using. (PX7063 (Berry (Illumina) IHT at 31)). For example, after Illumina closed its acquisition of Grail, Illumina added a new account manager, Linda Ray, to handle the Grail account. (Berry (Illumina) Tr. 931). Linda Ray reports to Ms. Abernathy, who reports to Curtis Fiedler, who reports to Ms. Berry. (Berry (Illumina) Tr. 931-32). Therefore, this Court should disregard the proposed finding.

> 1040.4 Fourth, Illumina uses document control processes to keep confidential documents from certain individuals within Illumina. (Goswami (Illumina) Tr. 3229–30.) These processes include software access controls, as well as storing confidential physical documents in a separate and controlled location. (Goswami (Illumina) Tr. 3230–31.)

Response to Finding No. 1040.4

The proposed finding is vague because it fails to define or describe what these "document control processes," "software access controls," "storing confidential physical documents," and

"separate and controlled location" entail. The proposed finding is also vague because it fails to define or describe which "certain individuals within Illumina" Respondents are referring to. The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, and does not cite to any specific documents or written policies and procedures to support Respondents' proposed "fact."

The proposed finding is misleading to the extent it implies Illumina executives are not privy to confidential information provided by customers. Illumina's Senior Vice President and General Manager of the Americas, Ms. Nicole Berry, testified that she is "responsible for the customer-facing functions in the United States, Canada and Latin America." (PX7063 (Berry (Illumina) IHT at 14)). "Customer-facing functions" means Illumina's "sales teams and it's… service and support teams…" (PX7063 (Berry (Illumina) IHT at 31)). Ultimately, all sales managers for the Americas report to Ms. Berry, thus she has the ability to view confidential information from all customers. (*See* PX7063 (Berry (Illumina) IHT at 31, 40-41)). Therefore, this Court should disregard the proposed finding.

> 1040.5 Fifth, if someone requests access to a protected document, the person responsible for the document receives legal guidance before granting access to someone else. (Goswami (Illumina) Tr. 3230.)

Response to Finding No. 1040.5

The proposed finding is vague because it fails to define or describe what the phrases "person responsible for the document," "legal guidance," "granting access," and "someone else" mean. The proposed finding is confusing and unclear as to who is "responsible for the document," who provides "legal guidance," and who is being granted "access."

The proposed finding is misleading to the extent it implies that Illumina does not show confidential documents to Illumina employees. Respondents cite to no evidence or written policy

and procedure, other than the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, to support Respondents' proposed "fact."

The proposed finding is also misleading to the extent it implies Illumina's "protected document" process actually limits who can view a particular document. Respondents cite to no evidence or written policy and procedure, other than the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

> 1040.6 In addition, Illumina often requires a separate internal confidentiality agreement for particular projects that require confidentiality. (Goswami (Illumina) Tr. 3232.)

Response to Finding No. 1040.6

The proposed finding is vague because it fails to define and describe what "a separate internal confidentiality agreement" and "particular projects" entail. The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, and does not cite to any specific documents or written policies and procedures to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

> 1040.7 High-level executives at Illumina generally do not have access to customer databases. (Berry (Illumina) Tr. 918–19; Goswami (Illumina) Tr. 3232.)

Response to Finding No. 1040.7

The proposed finding is vague because it fails to describe or define who these "high-level executives" include. The proposed finding is also vague because it fails to define or describe what "access" and "customer databases" include.

The proposed finding is misleading to the extent it implies Illumina's executives do not have access to customer information. Illumina's Senior Vice President and General Manager of the Americas, Ms. Nicole Berry, testified that she is "responsible for the customer-facing functions in the United States, Canada and Latin America." (PX7063 (Berry (Illumina) IHT at 14)). "Customer-facing functions" means Illumina's "sales teams and it's… service and support teams…" (PX7063 (Berry (Illumina) IHT at 31)). Ultimately, all sales managers for the Americas report to Ms. Berry, thus she has the ability to view confidential information from all customers. (*See* PX7063 (Berry (Illumina) IHT at 31, 40-41)). Therefore, this Court should disregard the proposed finding.

> 1040.8 These practices are standard in the industry and they are generally accepted by companies like Thermo Fisher that serve multiple clients in the same industry. (Goswami (Illumina) Tr. 3228–29.)

Response to Finding No. 1040.8

The proposed finding is vague because it fails to define and describe what the "standard in the industry" is and what "industry" Respondents are referring to. The proposed finding is misleading to the extent it refers to Thermo Fisher but provides no testimony or documentary evidence from Thermo Fisher to support it. Even if Thermo Fisher does have similar "practices" as Illumina, it does not mean that these "practices" are an industry standard.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami, and does not cite to any specific documents or written policies and procedures to support Respondents' proposed "fact." Therefore, this Court should disregard the proposed finding.

1041. [redacted]

Response to Finding No. 1041

[redacted]

[redacted]

1041.1 Firewalls are not novel or unusual. [redacted] *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In*

re Evanston Northwestern Healthcare Corp. Final Order) at 6; RX3319 (Highmark Health Competitively Sensitive Information Policy) at 2–9; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4; Fielder, Tr. 4488 (noting that FMI has firewalls and complies with them)) These types of firewalls have been implemented with success by the FTC (and other antitrust agencies or regulatory agencies) in vertical transactions, and these provisions can be effectively implemented. (RX6002 (Guerin-Calvert Trial Dep. at 81–82); PX7138 (Scott Morton Trial Dep. at 294); *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In re Evanston Northwestern Healthcare Corp.* Final Order) at 6; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4.)

Response to Finding No. 1041.1

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1041.2 [redacted]

Response to Finding No. 1041.2

[redacted]

[redacted]

[redacted]

1041.3 Illumina is very familiar with how to set up and operate these types of confidentiality procedures because it already shields confidential information between customers in similar fields. (Goswami (Illumina) Tr. 3231.)

Response to Finding No. 1041.3

The proposed finding is vague because it fails to define or describe what "types of confidentiality procedures" and what "similar fields" it is referring to. Additionally, nowhere in the Open Offer is the term "confidential information" defined. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021)). Even Illumina executive and Open Offer signatory testified that the Open Offer does not define what constitutes "confidential information." (Berry (Illumina) Tr. 716-18).

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President of Corporate Development and Strategic Planning, Joydeep Goswami. No customer testimony is cited to support the "fact" that Illumina can implement an effective firewall.

The proposed finding is misleading to the extent it implies that Illumina has effectively implemented a firewall in the past. Illumina's behavior in the NIPT business showcases how Illumina cannot in practice keep an effective firewall in place. [redacted]

[redacted]

1041.4 Illumina is currently implementing the confidentiality provisions of the Open Offer by operating GRAIL as a completely separate and distinct organization and by thoroughly reviewing any interface points with GRAIL. (Berry (Illumina) Tr. 917–18.)

Response to Finding No. 1041.4

This proposed finding is vague and misleading. The proposed finding is vague because the terms "completely separate" and "interface points" are undefined and unclear. The proposed finding is misleading because it relies solely on the self-serving testimony of an Illumina executive. The proposed finding that Illumina and Grail are being operated "completely separately" is also against the weight of the evidence. Ms. Berry testified that the new account manager in charge of Grail's account ultimately reports to Ms. Berry. (CCFF ¶¶ 4756-57).

[redacted]

Additionally, several customers have raised concerns over the Open Offer's confidentiality provision and Illumina's ability to implement an effective firewall. [redacted] Guardant's Mr. Getty testified that Illumina's firewall provision does "not at all" alleviate Guardant's concerns about the sharing of

competitively sensitive information with Illumina. (PX7040 (Getty (Guardant) IHT at 188)). Mr. Getty testified that "individuals on [Illumina's] executive team have traded back and forth already. . . . There are individuals – you know, Illumina was an early investor in Grail, and there are individuals who are on the executive team at Illumina who hold large stakes in Grail." (PX7040 (Getty (Guardant) IHT at 188-89)). Mr. Getty of Guardant testified that it is difficult for Guardant to know whether someone from Illumina's sequencing business has spoken with someone in Grail's business. (PX7105 (Getty (Guardant) Dep. at 79-80)). Therefore, this Court should disregard the proposed finding.

> 1041.5 The firewall between Illumina and GRAIL will have the characteristics of an effective firewall because it will provide at least the essential features common to past successful firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 85).) Specifically, the firewall provides for monitoring and auditing, methods to report violations and consequences for violations. (RX6002 (Guerin-Calvert Trial Dep. at 85).)

Response to Finding No. 1041.5

The proposed finding is vague because it fails to define or describe what the "characteristics of an effective firewall" are. The proposed finding is vague because it fails to explain or describe what the "essential features common to past successful firewalls" includes.

[redacted]

[redacted]

1042. The confidentiality and firewall provisions directly address the foreclosure concerns that have been raised regarding Illumina's ability to make use of customer Confidential Information to disadvantage GRAIL rivals. (*See* RX6002 (Guerin-Calvert Trial Dep. at 79–80).)

Response to Finding No. 1042

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here, Respondents cite Ms. Guerin-Calvert as the sole source supporting the finding, in

contravention of this Court's Order. The Court should disregard this evidence.

Further, this proposed finding is vague and misleading. The proposed finding is vague because "foreclosure concerns" is undefined. The proposed finding is misleading because it purports to speak to all concerns raised but relies solely on the self-serving testimony of Respondents' paid expert, with no corroboration from Illumina's customers. On the contrary, several customers have raised concerns over the Open Offer's confidentiality provision and Illumina's ability to implement an effective firewall. [redacted] Guardant's Mr. Getty testified that Illumina's firewall provision does "not at all" alleviate Guardant's concerns about the sharing of competitively sensitive information with Illumina. (PX7040 (Getty (Guardant) IHT at 188)). Mr. Getty testified that "individuals on [Illumina's] executive team have traded back and forth already. . . . There are individuals – you know, Illumina was an early investor in Grail, and there are individuals who are on the executive team at Illumina who hold large stakes in Grail." (PX7040 (Getty (Guardant) IHT at 188-89)). Mr. Getty of Guardant testified that it is difficult for Guardant to know whether someone from Illumina's sequencing business has spoken with someone in Grail's business. (PX7105 (Getty (Guardant) Dep. at 79-80)).

[redacted]

8. **Enforcement**

1043. The Open Offer contains enforcement provisions including a biannual audit and a commitment to binding arbitration in the event of a dispute. (deSouza (Illumina) Tr. at 2405, 2438; PX0064 (Illumina) at 10–11; RX3935 (Illumina) at 3.)

Response to Finding No. 1043

[redacted]

[redacted]

[redacted]

1044. The enforcement terms of the Open Offer provide Illumina's clinical oncology customers with effective monitoring and enforcement mechanisms to ensure compliance with the Open Offer terms and to effectuate its purpose of ensuring that Illumina cannot materially disadvantage GRAIL rivals post-merger. (RX6002 (Guerin-Calvert Trial Dep. at 22–23).) The very public aspect of the Open Offer can also bolster compliance. (*See* RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

Response to Finding No. 1044

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here, Respondents cite Ms. Guerin-Calvert as the sole source supporting the finding, in contravention of this Court's Order. The Court should disregard this evidence.

To the extent the proposed finding or Ms. Guerin-Calvert's testimony purport to interpret the terms of the Open Offer, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Further, this proposed finding is vague and misleading. The proposed finding is vague

because the term "effective monitoring and enforcement mechanisms" is undefined. The proposed finding is misleading because it purports to speak to concerns raised by customers but relies solely on the self-serving testimony of Respondents' paid expert, with no corroboration from Illumina's customers. On the contrary, customers have raised concerns over the ability to monitor and enforce the terms of the Open Offer. (*See* CCFF ¶¶ 4804-42; 4867-78).

Specifically, several customers have raised concerns over the Open Offer's confidentiality provision and Illumina's ability to implement an effective firewall. [redacted] Guardant's Mr. Getty testified that Illumina's firewall provision does "not at all" alleviate Guardant's concerns about the sharing of competitively sensitive information with Illumina. (PX7040 (Getty (Guardant) IHT at 188)). Mr. Getty testified that "individuals on [Illumina's] executive team have traded back and forth already. . . . There are individuals – you know, Illumina was an early investor in Grail, and there are individuals who are on the executive team at Illumina who hold large stakes in Grail." (PX7040 (Getty (Guardant) IHT at 188-89)). Mr. Getty of Guardant testified that it is difficult for Guardant to know whether someone from Illumina's sequencing business has spoken with someone in Grail's business. (PX7105 (Getty (Guardant) Dep. at 79-80)).

[redacted]

This proposed finding is also misleading to the extent it implies that Illumina's breach of the Open Offer would harm Illumina's reputation. If customers are able to discover a potential breach by Illumina of the Open Offer, the Open Offer explicitly provides that they must submit

the matter to "confidential binding arbitration." (*See* PX0064 at 008). Because enforcement of the Open Offer is confidential, other customers and industry participants would not learn of the breach. Thus, Illumina ensured, through its unilaterally imposed contractual terms, that its reputation cannot be harmed if it breaches the Open Offer. In addition, Illumina can breach the Open Offer in subtle ways that will likely go undetected. [redacted]

In addition, the weight of the evidence shows that Illumina's reputation among its customers is already poor. [redacted] Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and "people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

Further, Illumina does not care much about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

1045. The audit and arbitration provisions of the Open Offer play complementary roles to address the potential foreclosure concerns that have been raised. (RX6002 (Guerin-Calvert Trial Dep. at 89–90).) The audit provision assures customers that they will have access to the necessary information to ensure that Illumina abides by its obligations, and the arbitration provision allows for a mechanism to resolve any disputes that could arise. (RX6002 (Guerin-Calvert Trial Dep. at 89–90).)

Response to Finding No. 1045

The proposed finding is vague because it fails to define or describe what "complementary roles" and foreclosure concerns" mean.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here, Respondents cite Ms. Guerin-Calvert as the sole source supporting the finding, in contravention of this Court's Order. The Court should disregard this evidence.

To the extent the proposed finding or Ms. Guerin-Calvert's testimony purport to interpret the terms of the Open Offer, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

This proposed finding is misleading because it purports to speak to the concerns of Illumina's customers but relies solely on the self-serving testimony of Respondents' paid expert, with no corroboration from customers. Customers have testified to their concerns regarding the audit and arbitration provisions of the Open Offer. [redacted]

The proposed finding is misleading to the extent it implies that Illumina cannot breach these terms. As [redacted]

[redacted]

Ultimately, as [redacted]

This proposed finding is also misleading to the extent it implies that Illumina's customers will be able to enforce the terms effectively. Illumina's customers have nowhere else to go and Illumina's actions to foreclose rivals may go undetected. [redacted]

1046. [redacted]

Response to Finding No. 1046

[redacted]

[redacted]

[redacted]

a. Audits

1047. The Open Offer requires Illumina to engage in a biannual audit to ensure compliance with the Open Offer. (deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Further, if a customer has a good-faith basis for alleging that Illumina is in breach of the Open Offer, Illumina will engage an auditor to assess the customer's allegation separate from the biannual audits. (PX0064 (Illumina) at 10.)

Response to Finding No. 1047

[redacted]

[redacted]

[redacted]

[redacted]

1047.1 The Open Offer requires Illumina to conduct a bi-annual audit "by an independent third-party auditor selected by Illumina from among the 'Big 4' accounting firms to audit Illumina's compliance with the commitments set forth herein." (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

Response to Finding No. 1047.1

The proposed finding is misleading to the extent it implies Respondents have engaged with an auditor or determined the specific procedures by which the auditor will abide. (*See* CCFF ¶¶ 4858-66). The proposed finding is also misleading to the extent it implies that the customer will get to approve the auditor Illumina selects. Illumina's own executive and Open Offer signatory, Nicole Berry, testified that she did not know whether a customer would have to give approval before the auditor has access to their confidential information. (PX7076 (Berry (Illumina) Dep. at 290-91)).

[redacted]

[redacted]

[redacted]

1047.2 The Open Offer requires that "[t]o the extent Customer has a good faith basis for alleging that Illumina is in breach of a commitment contained herein, Illumina shall engage an auditor to assess Customer's allegation separate from and in addition to Illumina's [biannual] audit." (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

Response to Finding No. 1047.2

The proposed finding is vague because it fails to define or describe what a "good-faith basis" is. Additionally, nowhere in the Open Offer or its amended terms is the phrase "good-faith basis" define. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021); RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). Even Illumina executive and Open Offer signatory, Nicole Berry, testified that she did not know specifically who makes the determination of whether a customer's allegation rises to a good faith basis. (PX7076 (Berry (Illumina) Dep. at 284-85)).

[redacted]

[redacted]

[redacted]

[redacted]

1047.3 Mr. deSouza testified that, as Illumina's CEO, he does not have a problem with "raising the hood, and inspecting what's going on under there". (deSouza (Illumina) Tr. 2452.)

Response to Finding No. 1047.3

This proposed finding is vague because the terms "raising the hood" and "inspecting what's going on under there" are unclear and undefined.

This proposed finding is also misleading to the extent it purports to demonstrate that Illumina will do what is best for customers. The weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted]

1047.4 [redacted] Nonetheless, to provide customers with even greater security, the Open Offer provides for regular audits *twice* a year (as well as additional audits when customers have a good-faith basis for alleging breach). (RX3935 (Illumina) at 3.)

Response to Finding No. 1047.4

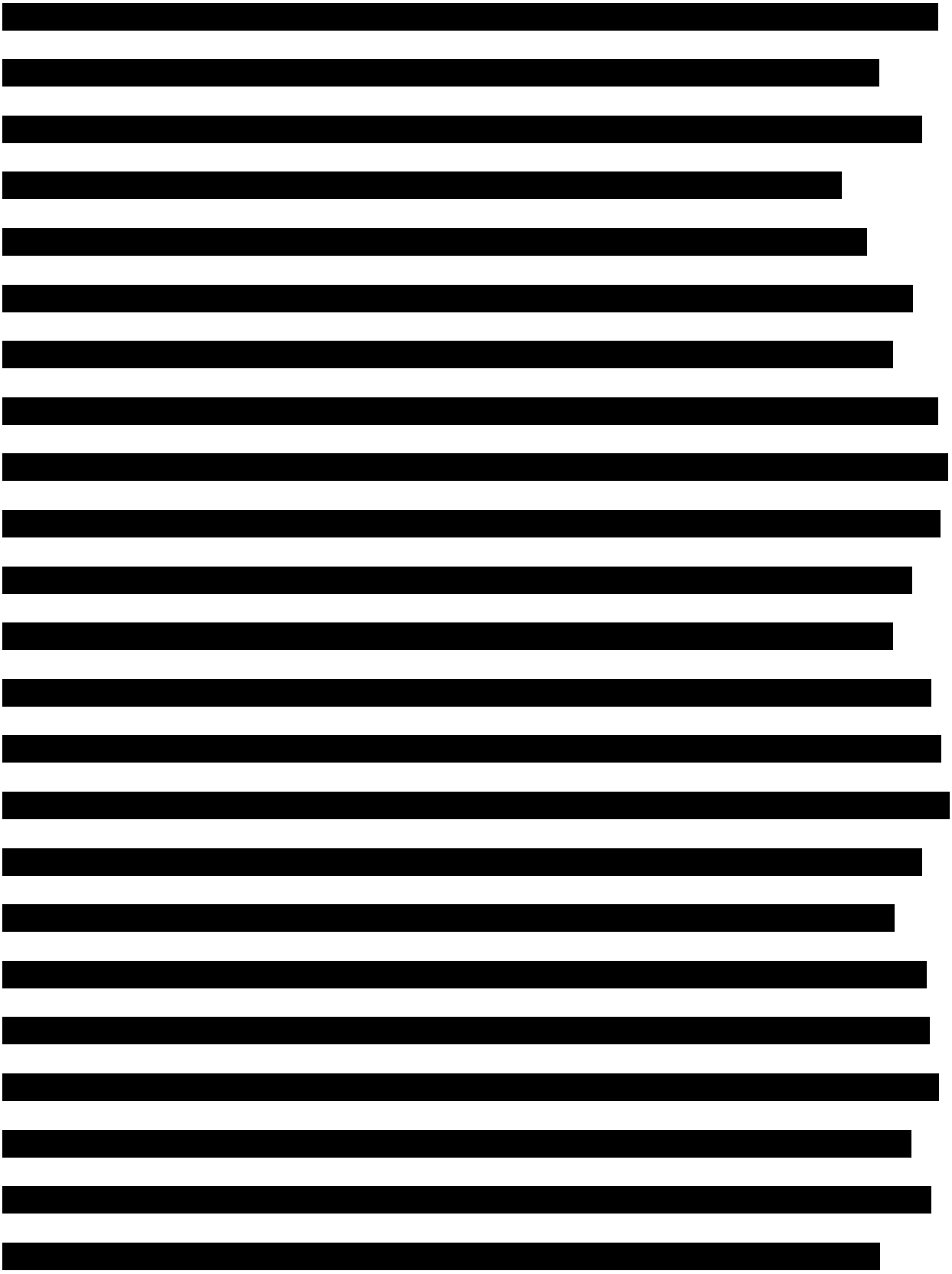
[redacted]

1048. Illumina is obligated to provide customers with a written report confirming compliance with the Open Offer's commitments. (PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) Additionally, customers must be promptly notified, within 10 days, of any potential noncompliance. (deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.)

Response to Finding No. 1048

The proposed finding is vague because it fails to explain or describe what will be included in this "written report confirming compliance."

[redacted]



[redacted]

1048.1 The Open Offer requires that "Illumina will provide Customers with a written report (with reasonable redactions) confirming compliance with the commitments set forth herein." (PX0064 (Illumina) at 10.)

Response to Finding No. 1048.1

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires," is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

This proposed finding is also vague because the term "reasonable redactions" is unclear and is not defined in the Open Offer letter. Therefore, this Court should disregard the proposed finding.

1048.2 The Open Offer requires that "[i]n addition to providing the written report, in the event of any finding of potential noncompliance with Illumina's performance under the Supply Agreement, Customer shall be notified within 10 days of identifying such a finding of potential noncompliance." (RX3935 (Illumina) at 3.)

Response to Finding No. 1048.2

Complaint Counsel acknowledges that Respondents' Amended Open Offer letter dated September 8, 2021 includes the quoted language. Respondents' revised the terms of their Open Offer letter in the middle of trial. Moreover, the term "requires," is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

1049. Illumina is committed to cooperating with any audits. (PX7076 (Berry (Illumina) Dep. at 287–88); PX0064 (Illumina) at 10.)

Response to Finding No. 1049

Complaint Counsel restate their objections raised in the cited testimony that the form of the questions was improper, and that counsel asked an incomplete hypothetical. (PX7076 (Berry (Illumina) Dep. at 287-88)).

This proposed finding is misleading to the extent it implies that the referenced audits are sufficient to assuage customer concerns. To the contrary, [redacted]

This proposed finding is also misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

1049.1 The Open Offer requires that "Illumina shall provide cooperation, including access to necessary books and records, in support of any audit conducted." (PX0064 (Illumina) at 10.)

Response to Finding No. 1049.1

The proposed finding is vague because it is fails to define or describe what "cooperation" and "necessary books and records" mean. It is unclear what amounts to a book and a record under this term of the Open Offer. Additionally, it is unclear what amount to "necessary" and who makes this determination.

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

Complaint Counsel acknowledges that Respondents' Open Offer letter includes the quoted language. However, the term "requires" finding is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

This proposed finding is also misleading to the extent it implies that the referenced audits are sufficient to assuage customer concerns. [redacted] Therefore, this Court should disregard the proposed finding.

1049.2 Illumina will also pay for any audits. (Berry (Illumina) Tr. 921; PX7076 (Berry (Illumina) Dep. at 284, 285).)

Response to Finding No. 1049.2

The proposed finding is misleading to the extent it implies that the Open Offer states that "Illumina will [] pay for any audits." Nowhere in the Open Offer or its amended terms does it state that Illumina will pay for any audit.

This proposed finding is inherently speculative and unsupported; it is also misleading. The proposed finding is speculative and unsupported because it relies solely on the self-serving testimony of an Illumina executive. To the extend the proposed finding or Ms. Berry's testimony purport to interpret the Open Offer, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

This proposed finding is misleading to the extent it implies that the referenced audits are sufficient to assuage customer concerns. To the contrary, [redacted]

[redacted]

1050. Audit provisions in general are common and can be effectively implemented. (RX6003 (Rock Trial Dep. at 29–32, 35–36, 45–46).)

Response to Finding No. 1050

The proposed finding is misleading to the extent it implies that whether audit provisions are common has any bearing on whether the Open Offer's audit provision in this case restores the loss of competition that will take place post-acquisition.

[redacted]

[redacted]

[redacted]

1050.1 Audits like those provided for in the Open Offer can effectively address allegations of breach. (RX6003 (Rock Trial Dep. at 31–32).)

Response to Finding No. 1050.1

[redacted]

The proposed finding is misleading to the extent it implies that customer concerns regarding enforceability of the Open Offer because of a breach are resolved by the audit provision. MCED customers testified that if the auditor, selected and paid by Illumina, does in fact find Illumina in noncompliance with the Open Offer, customers are concerned with getting into a disagreement with their sole supplier. (*See* CCFF ¶¶ 4941-43). Guardant's Mr. Getty

testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). Mr. Getty explained how "nearly impossible" enforcement of a contract with Illumina is when he testified "[a] contract is only as good as it is enforceable. And ultimately, [Guardant's ability] to investigate adherence to the terms of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)). Mr. Getty further testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). Mr. Fiedler testified that being in a contractual dispute with an essential supplier for FMI, such as Illumina, would be a "very grave concern if this would impact deliveries." (PX7118 (Fiedler (FMI) Dep. at 85-86) ("Q. Do you see any issues with being in a contractual dispute with an essential supplier for FMI? [Objections] A. I think the main concern is that as long as the delivery continues during that dispute, then as I said, it's the extra service of the extra flexibility that might be missing. It would be of very grave concern if this would impact deliveries.")).

[redacted]

[redacted]

1050.2 Independent auditors are fully capable of assisting Illumina in developing the appropriate procedures, controls and reporting to allow Illumina and contracting customers the ability to monitor compliance with the terms of the Open Offer. (RX6003 (Rock Trial Dep. at 31).)

Response to Finding No. 1050.2

[redacted]

[redacted]

1050.3 Independent auditors can be effective in (1) examining an entity's compliance with various terms of contracts, (2) performing agreed-upon procedures related to an entity's compliance with specific terms, and (3) performing agreed-upon procedures related to an entity's internal controls over compliance with specified terms. (RX6003 (Rock Trial Dep. at 29–30).)

Response to Finding No. 1050.3

[redacted]

[redacted]

1050.4 The role of an independent auditor is similar to that of a monitor and can perform the same essential oversight role in many respects. (RX6003 (Rock Trial Dep. at 32).)

Response to Finding No. 1050.4

[redacted]

[redacted]

[redacted]

1050.5 Audit provisions are common in commercial contracts, supply agreements, credit agreements, service contracts and regulatory compliance matters. (RX6003 (Rock Trial Dep. at 35–36).)

Response to Finding No. 1050.5

[redacted]

[redacted]

1050.6 Audit provisions are often used by regulatory agencies like DOJ and FTC to monitor both financial and non-financial terms, like those related to quality, confidentiality or firewalls. (RX6003 (Rock Trial Dep. at 36, 45–46).)

Response to Finding No. 1050.6

The proposed finding is misleading to the extent it implies that the DOJ and FTC's use of audit provisions has any bearing on whether the Open Offer's audit provision restores the loss of competition that will take place post-acquisition. Respondents provide no facts or circumstances explaining the cases where regulatory agencies used audit provisions and how those cases have any resemblance to Illumina's acquisition of Grail. In this case, customers testified to the inability of the Open Offer's audit provision to resolve their concerns over Illumina's ability to disadvantage Grail's rivals. (*See* CCFF ¶¶ 4843-78).

[redacted]

1050.7 The Public Company Accounting Oversight Board has published standards to ensure quality for compliance audits like those provided for in the Open Offer. (RX6003 (Rock Trial Dep. at 45).)

Response to Finding No. 1050.7

The proposed finding is misleading to the extent it implies that the Open Offer or Illumina's selected auditor will follow the standards published by the "Public Company Accounting Oversight Board." Additionally, nowhere in the Open Offer or its amended terms does it state that Illumina is required to follow the Public Company Accounting Oversight Board standards. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021); RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

[redacted]

1050.8 Large CPA firms like the Big 4 have the relevant knowledge and experience to conduct an effective compliance audit. (RX6003 (Rock Trial Dep. at 45).) Additionally, CPAs very frequently review compliance with contract provisions and audit the effectiveness of internal controls. (RX6003 (Rock Trial Dep. at 45).) This experience can increase the effectiveness and value of an audit over time. (RX6003 (Rock Trial Dep. at 45).)

Response to Finding No. 1050.8

The proposed finding is vague because it fails to define or describe what an "effective compliance audit" means.

The proposed finding is misleading to the extent it implies that large CPA firms having "relevant knowledge and experience to conduct an effective compliance audit" proves anything about Illumina's Open Offer. Large CPA firms' knowledge and experience does not prove that the Open Offer's audit provision in this case restores the loss of competition that will take place post-acquisition.

The proposed finding is misleading to the extent it implies Respondents know how the Open Offer, and in particular the audit provision, will function. Respondents have yet to operationalize the Open Offer, despite the Open Offer becoming operative at the time the

Acquisition closed on August 18, 2021, prior to trial. (*See* Op. Stmt. (Resp.) Tr. 84-85; deSouza (Illumina) Tr. 2234; Bishop (Grail) Tr. 1353; Berry (Illumina) Tr. 857); (PX0064 at 003 (Illumina, Open offer Letter, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding.

1051. The Open Offer's audit provision allows for effective audits of Illumina's compliance with the Open Offer's requirements. (RX6003 (Rock Trial Dep. at 31, 35, 44 –45, 50–72).)

Response to Finding No. 1051

The proposed finding is vague because it fails to define or describe what "effective audits" mean.

[redacted]

[redacted]

[redacted]

1051.1 The Open Offer's audit provision will act as a preventive measure to encourage compliance. (RX6003 (Rock Trial Dep. at 44).) The Open Offer's audit provision will also serve as a detective measure by finding and reporting instances of noncompliance. (RX6003 (Rock Trial Dep. at 44–45).)

Response to Finding No. 1051.1

[redacted]

[redacted]

[redacted]

1051.2 Audits of the Open Offer provisions on pricing and access to products and services can ensure that Illumina's customers are not disadvantaged by enabling Illumina to improve its procedures to help prevent instances of noncompliance and by providing customers with information to help them decide whether arbitration is necessary. (RX6003 (Rock Trial Dep. at 62–63, 66–67).)

Response to Finding No. 1051.2

[redacted]

[redacted]

[redacted]

[redacted]

1051.3 Audits of the Open Offer firewall provision will effectively ensure customers are not disadvantaged even if it does not address every customer concern because the audits provide information to improve Illumina's internal procedures to help prevent instances of non-compliance and to help customers decide whether action is necessary to remedy non-compliance. (RX6003 (Rock Trial Dep. at 71–72).)

Response to Finding No. 1051.3

[redacted]

[redacted]

[redacted]

1052. Illumina has a contract with Deloitte Consulting to help them operationalize the terms of the Open Offer. [redacted] This engagement will help Illumina improve its systems to allow for maximally effective audits. (PX7135 (Rock Dep. at 90).)

Response to Finding No. 1052

[redacted]

1052.1 Bringing in an outside consultant to assist with operationalizing the Open Offer is a positive step from an audit perspective. (PX7135 (Rock Dep. at 91–93).)

Response to Finding No. 1052.1

[redacted]

[redacted]

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite Mr. Rock as the only source of evidence supporting the proposed finding, in contravention of this Court's Order. This Court should disregard this evidence.

[redacted]

1053. In addition to the audit provision, Illumina also has unilaterally committed to grant the FTC similar monitoring, oversight, and access authority in connection with the proposed acquisition through the Consent Principles. (RX3155 (Illumina) at 4.) The Consent Principles, for example, authorize the FTC to appoint a monitor trustee, to require an annual verified written report of Illumina's manner and form of compliance, and to access to Illumina's books, records, directors, officers, and employees. (RX3155 (Illumina) at 4–5.)

Response to Finding No. 1053

This proposed finding is misleading to the extent it implies that the purported commitments are sufficient to assuage competitive concerns about the acquisition but relies solely on Illumina's own self-serving unilateral statements. The proposed finding is also misleading because although the document purports to allow the FTC to appoint a monitor, it also limits that monitor's powers. (*See* (RX3155 (Illumina) at 4)).

The proposed finding is misleading to the extent it implies that behavior remedies, such

as implementing a monitor, are preferred or accepted by the FTC. As explained in Complaint Counsel's post-trial brief, "structural remedies are preferred for Section 7 violations." *In re Evanston Northwestern Healthcare Corp.*, 2007 WL 2286195, *77 (Aug. 6, 2007) ((citing *United States v. E.I. du Pont de Nemours & Co.,* 366 U.S. 316, 329 (1961)). This is because a structural remedy is "simple, relatively easy to administer, and sure" to preserve competition. *du Pont 1961*, 366 U.S. at 331. There are also "greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution." *Evanston Northwestern*, 2007 WL 2286195, at *77 In other words, implementing a monitor is an expensive endeavor that does not restore the loss of competition that will take place post-acquisition, and these costs will fall on American taxpayers.

[redacted]

Therefore, this Court should disregard the proposed finding.

b. Arbitration

1054. Illumina also agrees to binding arbitration in the event that a dispute arises under the agreement. (Rabinowitz (Natera) Tr. 444; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).)

Response to Finding No. 1054

This proposed finding is vague and misleading. It is vague because it does not define what constitutes a "dispute" under the agreement.

To the extent the Open Offer letter contains an arbitration provision, the proposed finding is misleading because it omits that the arbitration provision in the Open Offer provides for "confidential" arbitration. (PX0064 at 10 (Illumina Open Offer Agreement, March 29, 2021)).

The proposed finding is misleading to the extent it implies that "binding arbitration" resolves customers concerns regarding their ability to monitor and enforce the terms Open Offer.

(*See* CCFF ¶¶ 4804-4946).

This proposed finding is also misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

> 1054.1 The Open Offer explicitly requires that "[i]f any dispute arises from or relates to this Supply Agreement, including as a result of a dispute over terms in a separate agreement that incorporates the terms herein (the "Dispute"), other than claims involving infringement, validity, or enforceability of Intellectual Property Rights (whether Illumina's or Customer's), or about the scope of Intellectual Property Rights in an agreement, Illumina and Customer (each a "party" and together the "parties") shall submit the matter to confidential binding arbitration to determine final terms and conditions of the supply agreement, or to settle the dispute as to the terms of a supply agreement." (PX0064 (Illumina) at 10.)

Response to Finding No. 1054.1

Complaint Counsel acknowledge that the Open Offer letter contains the quoted language. However, the term "requires" is misleading because it implies that Illumina cannot breach the terms of the Open Offer. [redacted]

1054.2 Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (deSouza (Illumina) Tr. 2460–61.)

Response to Finding No. 1054.2

The proposed finding relies solely on the self-serving testimony of Illumina's CEO, Francis deSouza. Respondents fail to cite to any customer testimony supporting the claim that Illumina "aims to get through any arbitration as fast as possible…" and Illumina "is open to soliciting feedback and improving the arbitration process."

The proposed finding is misleading to the extent it implies that the Open Offer arbitration provision and Illumina's intentions resolve customers concerns. MCED customers have testified to the issues with the Open Offer's arbitration provision. First, Arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Mr. Getty also testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)). Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering,

and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Ultimately, as Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)). Therefore, this Court should disregard the proposed finding.

> 1054.3 Prior to any binding arbitration, the Open Offer also provides for an immediate dispute resolution process: "Prior to submitting any matter to arbitration, Illumina and Customer shall each designate a contact having the proper authorization to resolve the Dispute in a final and binding fashion, who shall meet in person or by telephone for a period of thirty (30) days (or such other period of time as Illumina and the Customer shall mutually agree) in an attempt to resolve the Dispute in good faith." (PX0064 (Illumina) at 10.)

Response to Finding No. 1054.3

The proposed finding is vague because it fails to define or describe what "immediate" means. Nowhere in the Open Offer's arbitration provision is the term "immediate" used to describe the first step in the arbitration process.

The proposed finding is misleading to the extent it implies that this "immediate dispute resolution process" resolves customers concerns regarding arbitration with Illumina. MCED customers testified to their concerns regarding the Open Offer's arbitration provision. First, arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Illumina executive and Open Offer signatory, Ms. Berry, does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24). Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

An arbitration with Illumina will slow down the innovation of MCED tests. Guardant's Mr. Getty testified that arbitration with Illumina would slow down Guardant's innovation and

have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)). Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Ultimately, as Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)). Therefore, this Court should disregard the proposed finding.

1054.4 This immediate dispute resolution mechanism helps address any concern about the time and expense of arbitration. (RX6002 (Guerin-Calvert Trial Dep. at 90–91).)

Response to Finding No. 1054.4

The proposed finding is an improper use of an expert. This Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This Could should disregard this evidence.

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry to support Respondents' proposed "fact."

The proposed finding is misleading to the extent it implies that this "immediate dispute resolution process" resolves customers concerns regarding the time and expense of arbitration with Illumina. MCED customers testified to their concerns regarding the Open Offer's arbitration provision. First, arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the

different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Illumina executive and Open Offer signatory, Ms. Berry, does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24). Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

An arbitration with Illumina will slow down the innovation of MCED tests. Guardant's Mr. Getty testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)). Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Ultimately, as Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative

interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)). Therefore, this Court should disregard the proposed finding.

1054.5 Illumina's interest is to resolve any disputes under the Open Offer quickly. (deSouza (Illumina) Tr. 2460–61.)

Response to Finding No. 1054.5

The proposed finding is vague because it fails to explain why it is "Illumina's interest [] to resolve any disputes under the Open Offer quickly." The proposed finding relies solely on the self-serving testimony of Illumina CEO, Francis deSouza. Respondents fail to cite to any Illumina customer testimony to substantiate this claim.

[redacted]

[redacted]

[redacted]

[redacted]

1055. The arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief, and must follow the Commercial Arbitration Rules of the American Arbitration Association (AAA). (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3; deSouza (Illumina) Tr. 2451–52.)

Response to Finding No. 1055

The proposed finding is vague because it fails to define or describe what "the status quo prior to Illumina's breach" means. Additionally, nowhere in the Open Offer or its amended terms is "status quo prior to Illumina's breach" explained. (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3)). The proposed finding is vague because it fails to explain how the arbitrator will know whether a violation by Illumina has taken place.

The proposed finding is finding is misleading to the extent it implies the Illumina appointed arbitrator will take any particular actual if an Illumina breach is discovered. The amended terms of the Open Offer, presented in the middle of trial, states that the "Arbitrator *may* order any relief necessary" if Illumina is found to have "breached any provision of the Supply Agreement." (RX3935 (Illumina) at 3) (emphasis added). "May" is permissive and does not require the Arbitrator to take any particular action. Therefore, this Court should disregard the proposed finding.

> 1055.1 The Open Offer requires that "[i]f the Arbitrator determines that Illumina has breached any provision of the Supply Agreement, the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." (RX3935 (Illumina) at 3.)

Response to Finding No. 1055.1

Complaint Counsel acknowledges that Respondents' Amended Open Offer letter dated September 8, 2021 includes the quoted language. Respondents' revised the terms of their Open Offer letter in the middle of trial. Moreover, the term "requires," is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

The proposed finding is vague because it fails to define or describe what "the status quo prior to Illumina's breach" means. Additionally, nowhere in the Open Offer or its amended terms is "status quo prior to Illumina's breach" explained. (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3)). The proposed finding is vague because it fails to explain how the arbitrator will know whether a violation by Illumina has taken place.

The proposed finding is finding is misleading to the extent it implies the Illumina appointed arbitrator will take any particular actual if an Illumina breach is discovered. The amended terms of the Open Offer, presented in the middle of trial, states that the "Arbitrator *may* order any relief necessary" if Illumina is found to have "breached any provision of the Supply Agreement." (RX3935 (Illumina) at 3) (emphasis added). "May" is permissive and does not require the Arbitrator to take any particular action. Therefore, this Court should disregard the proposed finding.

1056. The arbitrator's decision is required to reflect the fact that the purpose of the Open Offer is to allay any concerns relating to the Illumina-GRAIL transaction. (RX3935 (Illumina) at 3.)

Response to Finding No. 1056

[redacted]

[redacted]

1056.1 Specifically, the Open Offer requires that "[i]n resolving any dispute under the Supply Agreement, the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the Supply Agreement is to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." (RX3935 (Illumina) at 3.)

Response to Finding No. 1056.1

[redacted]

[redacted]

1057. The arbitration provision addresses the foreclosure concerns that have been raised by providing for an independent entity to judge disputes that arise under the Open Offer. (RX6002 (Guerin-Calvert Trial Dep. at 88–91).)

Response to Finding No. 1057

The proposed finding is vague because it fails to explain or describe what these "foreclosure concerns" are. The proposed finding is vague because it fails to define or describe what "independent entity" means. It is unclear who gets to select this "independent entity" and what the recourse is if a customer does not like the "independent entity" selected.

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite Ms. Guerin-Calvert as the only source of evidence supporting the proposed finding, in contravention of this Court's Order. This Court should disregard this evidence.

This proposed finding is also misleading to the extent it implies that the arbitration provision addresses the concerns of customers or the Commission but relies solely on the self-serving testimony of Respondents' paid expert. To the contrary, MCED customers have testified to their concerns regarding the Open Offer's arbitration provision. (*See* CCFF ¶¶ 4934-50). Therefore, this Court should disregard the proposed finding.

1057.1 MCED test developers would not be disadvantaged relative to GRAIL while arbitration is taking place. (RX6002 (Guerin-Calvert Trial Dep. at 91–92).)

Response to Finding No. 1057.1

This Court ordered that experts shall not be cited to "support factual propositions that

should be established by fact witnesses or documents." (*See* Order on Post-Trial Findings at 3). Here Respondents cite Ms. Guerin-Calvert as the only source of evidence supporting the proposed finding, in contravention of this Court's Order. This Court should disregard this evidence.

This proposed finding is misleading to the extent it purports to speak to the concerns of Illumina's customers but relies solely on the self-serving testimony of Respondents' paid expert. To the contrary, MCED customers and Complaint Counsel's expert have testified to Illumina incentive to disadvantage Grail's rivals. (*See* generally CCFF ¶¶ 3079-3569). The Open Offer does not change Illumina's strong incentives to favor Grail. (*See* CCFF ¶¶ 4175-93).

This proposed finding is also misleading to the extent it purports to demonstrate that Illumina will do what is best for customers. The weight of the evidence shows that Illumina's reputation among its customers is poor. [redacted]

D. Status of the Open Offer

1058. [redacted]

Response to Finding No. 1058

[redacted]

[redacted]

1059. [redacted]

Response to Finding No. 1059

[redacted]

[redacted]

1060. [redacted]

Response to Finding No. 1060

[redacted]

[redacted]

1061. [redacted]

Response to Finding No. 1061

[redacted]

[redacted]

1062. [redacted]

Response to Finding No. 1062

[redacted]

[redacted]

1063. [redacted]

Response to Finding No. 1063

[redacted]

[redacted]

1064. [redacted]

Response to Finding No. 1064

[redacted]

1065. [redacted]

Response to Finding No. 1065

[redacted]

[redacted]

1066. [redacted]

Response to Finding No. 1066

[redacted]

[redacted]

1067. [redacted]

Response to Finding No. 1067

[redacted]

1068. [redacted]

Response to Finding No. 1068

[redacted]

[redacted]

1069. In addition to the protections afforded by the Open Offer, on February 26, 2021, Illumina presented the FTC with a set of unilateral behavior commitments in the form of consent principles ("the Consent Principles".) (RX3155 (Illumina).)

Response to Finding No. 1069

The proposed finding is vague and misleading in several ways. [redacted] Respondents have presented no evidence that the Consent Principles would fix these flaws or assuage customers' concerns about the Open Offer. [redacted]

[redacted]

Second, the proposed finding is misleading to the extent that it suggests the Consent Principles are legally binding. RX3155, which is undated, contains no signatures from Illumina representatives guaranteeing commitment to the proposed principles. RX3155 also does not specify how the Consent Principles would be enforced, beyond stipulating that (1) the FTC may appoint a "Monitor Trustee" to monitory any disputes, claims, or controversies, (2) Illumina would submit an annual "verified written report" on Illumina's compliance with the Consent Principles, and (3) Illumina would grant the FTC access to Illumina books, records, officers, directors, and employees. (RX3155 at 004-05 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)). However, RX3155 does not define the "standard terms and conditions regarding the Monitor Trustee's powers, duties, authority, and responsibilities," and it only guarantees the appointment of a Monitor Trustee for ten years. (RX3155 at 004 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)). RX3155 also does not specify how Illumina's annual compliance report would be "verified," either by customers, the FTC, or an independent third party. (RX3155 at 004 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)). Finally, RX3155 does not specify what the FTC's "written request" for access would require, how long Illumina would take to respond to non-interview requests, and who would determine which Illumina books, documents, and records fall under the category of "relating to any matters contained in this Order." (RX3155 at 005 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)).

Third, the proposed finding is misleading to the extent that it suggests Respondents would adhere to the unilateral behavioral commitments outlined in RX3155. [redacted]

[redacted]

The proposed finding is vague because the terms "protections afforded by the Open Offer" and "unilateral behavioral commitments" are ambiguous.

Additionally, Respondents' citation to RX3155 is in contravention of this Court's Order regarding post-trial findings. This Court ordered that "[w]hen citing to exhibits, the parties shall identify the document by the PX or RX number, followed by the name of the entity that produced the document, and the page number." (Order on Post-Trial Findings at 3). RX3155 is a seven-page document, and Respondents fail to provide a citation to specific page number or page range in contravention of the Court's Order. Thus, the Court should disregard this proposed evidence and the proposed finding.

> 1069.1 The Consent Principles would (i) permit the FTC to appoint a monitor trustee, (ii) provide for submission of an annual verified written report to the FTC regarding Illumina's compliance with the Consent Principles and (iii) grant FTC access to Illumina books, records, officers, directors and employees to determine or secure compliance with the Consent Principles. (RX3155 (Illumina) at 4–5.)

Response to Finding No. 1069.1

The proposed finding is vague and misleading in several ways. [redacted] Respondents have presented no evidence that the Consent Principles would fix these flaws or assuage customers' concerns about the Open Offer. [redacted]

[redacted]

Second, the proposed finding is misleading to the extent that it suggests the Consent Principles are legally binding. RX3155, which is undated, contains no signatures from Illumina representatives guaranteeing commitment to the proposed principles. RX3155 also does not specify how the Consent Principles would be enforced, beyond stipulating that (1) the FTC may appoint a "Monitor Trustee" to monitory any disputes, claims, or controversies, (2) Illumina would submit an annual "verified written report" on Illumina's compliance with the Consent Principles, and (3) Illumina would grant the FTC access to Illumina books, records, officers, directors, and employees. (RX3155 at 004-05 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)). However, RX3155 does not define the "standard terms and conditions regarding the Monitor Trustee's powers, duties, authority, and responsibilities," and it only guarantees the appointment of a Monitors Trustee for ten years. (RX3155 at 004 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)). RX3155 also does not specify how Illumina's annual compliance report would be "verified," either by customers, the FTC, or an independent third party. (RX3155 at 004 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)). Finally, RX3155 does not specify what the FTC's "written request" for access would require, how long Illumina would take to respond to non-interview requests, and who would determine which Illumina books, documents, and records fall under the category of "relating to any matters contained in this Order." (RX3155 at 005 (Illumina) (Consent Principles: Unilateral Behavioral Commitments)).

Third, the proposed finding is misleading to the extent that it suggests Respondents would adhere to the unilateral behavioral commitments outlined in RX3155. [redacted]

[redacted]

[redacted]

The proposed finding is vague because the terms "monitor trustee," "verified written report," and "access" are ambiguous. Therefore, this Court should disregard the proposed finding.

> 1069.2 Because the Consent Principles in essence convert the Open Offer into a consent format, the Consent Principles are consistent with the Open Offer. (RX6002 (Guerin-Calvert Trial Dep. at 95–96).)

Response to Finding No. 1069.2

The proposed finding is improper, misleading, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Deverka's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinion, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

The proposed finding is vague because the terms "in essence" and "consistent with" are ambiguous, and the term "consent format" is undefined. Therefore, this Court should disregard the proposed finding.

1069.3 The Consent Principles' additional provisions are also "FTC friendly" and add provisions that the FTC has previously used in their own consent provisions. (RX6002 (Guerin-Calvert Trial Dep. at 96).)

Response to Finding No. 1069.3

The proposed finding is improper, misleading, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Deverka's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinion, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

The proposed finding is vague because the term "FTC friendly" is ambiguous and undefined. Additionally, the proposed finding does not specify which provisions are "FTC friendly," which provisions the FTC has previously used, or what previous consent provisions are being referred to. The proposed finding does not describe the cases in which consent decrees were effectively used by the FTC in the past and how those matters compare to the Illumina-Grail case. The adequacy of a remedy depends on the specific facts and circumstances of a given case.

The proposed finding is misleading to the extent it implies that behavior remedies, such as implementing a monitor, are preferred or accepted by the FTC. As explained in Complaint Counsel's post-trial brief, "structural remedies are preferred for Section 7 violations." *In re*

Evanston Northwestern Healthcare Corp., 2007 WL 2286195, *77 (Aug. 6, 2007) ((citing *United States v. E.I. du Pont de Nemours & Co.,* 366 U.S. 316, 329 (1961)). This is because a structural remedy is "simple, relatively easy to administer, and sure" to preserve competition. *du Pont 1961*, 366 U.S. at 331. There are also "greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution." *Evanston Northwestern*, 2007 WL 2286195, at *77 In other words, implementing a monitor is an expensive endeavor that does not restore the loss of competition that will take place post-acquisition, and these costs will fall on American taxpayers. Therefore, this Court should disregard the proposed finding.

> 1069.4 The enforcement provisions under the Consent Principles, including the monitor trustee commitment, the annual report commitment and the FTC access commitment (as well as those provided in the Open Offer), represent a comprehensive set of enforcement provisions across typical consent decrees in the FTC's past practice. (RX6002 (Guerin-Calvert Trial Dep. at 97–98).)

Response to Finding No. 1069.4

The proposed finding is improper, misleading, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Deverka's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinion, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

The proposed finding is vague because the terms "comprehensive set of enforcement provisions" and "typical consent decrees" are ambiguous. The proposed finding does not specify, cite to, or provide examples of consent decrees "in the FTC's past practice." Additionally, the proposed finding does not specify which enforcement provisions provided in the Open Offer are referenced. The proposed finding does not describe the cases in which consent decrees were effectively used by the FTC in the past and how those matters compare to the Illumina-Grail case. The adequacy of a remedy depends on the specific facts and circumstances of a given case.

The proposed finding is misleading to the extent it implies that behavior remedies, such as implementing a monitor, are preferred or accepted by the FTC. As explained in Complaint Counsel's post-trial brief, "structural remedies are preferred for Section 7 violations." *In re Evanston Northwestern Healthcare Corp.*, 2007 WL 2286195, *77 (Aug. 6, 2007) ((citing *United States v. E.I. du Pont de Nemours & Co.,* 366 U.S. 316, 329 (1961)). This is because a structural remedy is "simple, relatively easy to administer, and sure" to preserve competition. *du Pont 1961*, 366 U.S. at 331. There are also "greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution." *Evanston Northwestern*, 2007 WL 2286195, at *77 In other words, implementing a monitor is an expensive endeavor that does not restore the loss of competition that will take place post-acquisition, and these costs will fall on American taxpayers. Therefore, this Court should disregard the proposed finding.

> 1069.5 The Consent Principles demonstrate that Illumina is willing to be subject to oversight by a monitor with respect to its compliance with the Open Offer terms. (RX6002 (Guerin-Calvert Trial Dep. at 98).)

Response to Finding No. 1069.5

The proposed finding is improper, misleading, and vague. The proposed finding is

improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Deverka's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinion, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

The proposed finding is vague because the terms "oversight" and "monitor" are ambiguous. Therefore, this Court should disregard the proposed finding.

E. [redacted]

1070. [redacted]

Response to Finding No. 1070

[redacted]

1071. [redacted]

Response to Finding No. 1071

[redacted]

1072. [redacted]

Response to Finding No. 1072

[redacted]

[redacted]

1072.1 Consent decrees are effective measures for resolving antitrust disputes and have been used by the FTC and other regulatory agencies for many years. (RX6002 (Guerin-Calvert Trial Dep. at 105).)

Response to Finding No. 1072.1

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert. Additionally, the proposed finding is vague because it does not describe the cases in which consent decrees were effectively used by the FTC and other regulatory agencies in the past and how those cases compare to the Illumina-Grail case. The adequacy of a remedy depends on the specific facts and circumstances of a given case.

The proposed finding is vague because it fails to define or describe what the phrases "effective measure" and "antitrust disputes" mean. The proposed finding is misleading to the extent the effectiveness of consent decrees in other, non-related cases, has any bearing on whether the consent order in this case restores the loss of competition that will take place post-acquisition. [redacted] Therefore, this Court should disregard the proposed finding.

F. The Open Offer Addresses All Potential Criticisms and Concerns that Complaint Counsel and Certain Customers Have Raised

1. Customers' Alleged Concerns Regarding the Open Offer Are Unreliable

1073. Kevin Conroy, the Chairman and Chief Executive Officer of Exact, criticized the Open Offer, but had not actually read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer requires Illumina to do. (Conroy (Exact/Thrive) Tr. 1725–27 ("Q. So you haven't read the open offer, right? A. That's what I just testified to.").)

Response to Finding No. 1073

The proposed finding is misleading to the extent it implies that Mr. Conroy is aware of Illumina's Open Offer and what concerns Exact has with it. [redacted]

[redacted]

The proposed finding is incorrect and misleading because it misstates Mr. Conroy's testimony. When Mr. Conroy was asked about specific terms in the Open Offer he responded that he did not "know the details to that level of the open offer…. [and] I don't know… to that level of specificity." (Conroy (Natera) Tr. 1725). Mr. Conroy did not testified that he did not know what was in the Open Offer in general. Additionally, Mr. Conroy testified while he hasn't "read the full open offer" it's been "describe to [Mr. Conroy] by counsel." (Conroy (Natera) Tr. 1725-26). Therefore, this Court should disregard the proposed finding.

> 1073.1 For example, Mr. Conroy did not know whether the Open Offer commits Illumina to providing Exact access for purchase to any Pre-Release Sequencing Product to which GRAIL or any For-Profit Entity has access. (Conroy (Exact/Thrive) Tr. 1726.)

Response to Finding No. 1073.1

[redacted]

[redacted]

[redacted]

1073.2 Mr. Conroy did not know whether the Open Offer commits Illumina to enter into a separate development agreement on commercially reasonable terms, including the design or modification of any Supplied Product. (Conroy (Exact/Thrive) Tr. 1726.)

Response to Finding No. 1073.2

[redacted]

[redacted]

1073.3 Mr. Conroy did not know whether the Open Offer requires Illumina to allocate supply in an equitable manner in the event of a supply shortage. (Conroy (Exact/Thrive) Tr. 1726.)

Response to Finding No. 1073.3

[redacted]

[redacted]

[redacted]

1073.4 Mr. Conroy did not know the substance of the Open Offer's intellectual property provisions. (Conroy (Exact/Thrive) Tr. 1728–29.)

Response to Finding No. 1073.4

[redacted]

[redacted]

[redacted]

1073.5 [redacted]

Response to Finding No. 1073.5

[redacted]

[redacted]

1073.5.1 [redacted]; PX8388 (Illumina) at 3.)

Response to Finding No. 1073.5.1

[redacted]

[redacted]

1073.5.2 [redacted]

Response to Finding No. 1073.5.2

[redacted]

[redacted]

1074. [redacted]

Response to Finding No. 1074

[redacted]

[redacted]

1074.1 [redacted]

Response to Finding No. 1074.1

[redacted]

[redacted]

[redacted]

[redacted]

1074.2 [redacted]

Response to Finding No. 1074.2

[redacted]

[redacted]

[redacted]

1074.3 [redacted]

Response to Finding No. 1074.3

[redacted]

[redacted]

1074.4 [redacted]

Response to Finding No. 1074.4

[redacted]

[redacted]

[redacted]

1074.5 [redacted]

Response to Finding No. 1074.5

[redacted]

[redacted]

1074.6 [redacted]

Response to Finding No. 1074.6

[redacted]

[redacted]

1075. [redacted]

Response to Finding No. 1075

[redacted]

[redacted]

[redacted]

1075.1 [redacted]

Response to Finding No. 1075.1

[redacted]

[redacted]

1075.2 [redacted]

Response to Finding No. 1075.2

[redacted]

[redacted]

1075.3 [redacted]

Response to Finding No. 1075.3

[redacted]

1075.4 Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and important contract for Guardant. (Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.)

Response to Finding No. 1075.4

[redacted]

1075.5 In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (Getty (Guardant) Tr. 2669.)

Response to Finding No. 1075.5

[redacted]

[redacted]

1076. [redacted]

Response to Finding No. 1076

[redacted]

[redacted]

2. The Open Offer Does Not Contain "Loopholes" and Is Likely To be An Effective Contract Over its 12–year Term

1077. Contrary to the testimony of certain customers, the Open Offer does not contain too many "loopholes" to be effective; it contains the economically necessary set of terms to prevent the alleged competitive harms arising from the merger in both the short and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

Response to Finding No. 1077

The proposed finding is vague because if fails to define or describe what "loopholes," and "economically necessary" means. Additionally, the proposed finding is vague because "short and the long term" is undefined.

[redacted]

[redacted]

1077.1 In concluding that Illumina would be able to materially disadvantage GRAIL rivals after the Transaction, Complaint Counsel's expert, Dr. Scott Morton, failed to evaluate the ability of Illumina to raise rivals' costs, impose harm or foreclose rivals under the Open Offer. (RX6002 (Guerin-Calvert Trial Dep. at 23–24).)

Response to Finding No. 1077.1

First, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Second, the proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Ms. Guerin-Calvert's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Ms. Guerin-Calvert's expert opinion, in contravention of this

Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the terms "materially disadvantage," "impose harm," and "foreclose rivals" are ambiguous. Therefore, this Court should disregard the proposed finding.

1077.2 [redacted]

Response to Finding No. 1077.2

[redacted]

[redacted]

[redacted]

1078. Contrary to the opinion of Dr. Scott Morton, the theory of incomplete contracts does not, from an economic standpoint, mean that contracts cannot be written or that parties cannot enter into contracts that address unforeseen circumstances. (RX6002 (Guerin-Calvert Trial Dep. at 99–102); RX6000 (Carlton Trial Dep. at 50, 84–85).)

Response to Finding No. 1078

First, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Second, the proposed finding is improper and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Ms. Guerin-Calvert's and Dr. Carlton's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Ms. Guerin-Calvert's and Dr. Carlton's expert opinions, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is vague because the term "theory of incomplete contract" is undefined. Additionally, the term "unforeseen circumstances" is ambiguous. Therefore, this Court should disregard the proposed finding.

1078.1 Contracts can be written to take away Illumina's ability to disadvantage GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 104–05).) Indeed, behavioral remedies like the Open Offer have been used by the FTC and DOJ since the 1970s in a wide variety of industries and cases. (RX6002 (Guerin-Calvert Trial Dep. at 105).) A

retrospective study by the FTC of many consent decrees in horizontal and vertical mergers found that behavioral remedies were effective in the mergers studied. (RX6002 (Guerin-Calvert Trial Dep. at 81–82).)

Response to Finding No. 1078.1

First, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Second, the proposed finding is improper, misleading, against the weight of the evidence and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Ms. Guerin-Calvert's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Ms. Guerin-Calvert's expert opinion, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is misleading to the extent that it suggests the Open Offer has been written to take away Illumina's ability to disadvantage GRAIL rivals, or that the Open Offer is similar to remedies that been used or deemed effective by the FTC or DOJ. The weight of the evidence shows that the Open Offer does not change Illumina's incentives to foreclose Grail's rivals. (CCFF ¶¶ 4175-4193), and it does not preclude Illumina from disadvantaging Grail's rivals (CCFF ¶¶ 4484-5012). Furthermore, neither Respondents' monitors nor an independent auditor can effectively monitor Illumina's compliance with the Open Offer (CCFF ¶¶ 4843-4927), and the Open Offer cannot be effectively enforced. (CCFF ¶¶ 4928-4950).

The proposed finding is misleading to the extent it implies that behavioral remedies are preferred or accepted by the FTC. As explained in Complaint Counsel's post-trial brief,

"structural remedies are preferred for Section 7 violations." *In re Evanston Northwestern Healthcare Corp.*, 2007 WL 2286195, *77 (Aug. 6, 2007) ((citing *United States v. E.I. du Pont de Nemours & Co.,* 366 U.S. 316, 329 (1961)). This is because a structural remedy is "simple, relatively easy to administer, and sure" to preserve competition. *du Pont 1961*, 366 U.S. at 331. There are also "greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution." *Evanston Northwestern*, 2007 WL 2286195, at *77 In other words, implementing a monitor is an expensive endeavor that does not restore the loss of competition that will take place post-acquisition, and these costs will fall on American taxpayers.

The proposed finding is vague because terms "behavioral remedies like the Open Offer," "wide variety of industries and cases," and "many consent decrees" are ambiguous. The proposed finding is vague because it fails to define or explain what this "retrospective study" is or where it can be found. Additionally, the proposed finding does not specify who GRAIL's rivals are. Therefore, this Court should disregard the proposed finding.

> 1078.2 Dr. Scott Morton's opinion that the Open Offer is inadequate because it cannot anticipate every contingency that could arise ignores the fact that this is true of all contracts. (RX6000 (Carlton Trial Dep. at 49–50).) In fact, Dr. Scott Morton assumes that, absent the merger, sophisticated contracts could be written that would enable the efficiencies of the merger but places no confidence in the Open Offer's ability to protect GRAIL rivals, even though the Open Offer is a private contract that is privately enforceable. (RX6000 (Carlton Trial Dep. at 49–50).)

Response to Finding No. 1078.2

[redacted]

[redacted]

1078.3 Under the theory of incomplete contracts, economists can still evaluate the terms of the Open Offer to determine whether the terms provide customers with adequate protection. (RX6002 (Guerin-Calvert Trial Dep. at 100–01).) Economists have evaluated the Open Offer and concluded that it is a comprehensive contract that sufficiently addresses and anticipates issues that are likely to arise over time. (RX6002 (Guerin-Calvert Trial Dep. at 21–22, 103–04); RX6000 (Carlton Trial Dep. at 84–85).)

Response to Finding No. 1078.3

First, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Second, the proposed finding is improper, misleading, against the weight of the evidence

and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Ms. Guerin-Calvert's and Dr. Carlton's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Ms. Guerin-Calvert's and Dr. Carlton's expert opinions, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is misleading to the extent that it suggests the Open Offer provides "adequate protection" to Illumina's customers. The weight of the evidence shows that the Open Offer does not change Illumina's incentives to foreclose Grail's rivals. (CCFF ¶¶ 4175-4193), and it does not preclude Illumina from disadvantaging Grail's rivals (CCFF ¶¶ 4484-5012). Furthermore, neither Grail's monitors nor an independent auditor can effectively monitor Illumina's compliance with the Open Offer (CCFF ¶¶ 4843-4927), and the Open Offer cannot be effectively enforced. (CCFF ¶¶ 4928-4950). [redacted]

The proposed finding is vague because the term "theory of incomplete contracts" is undefined, and the terms "adequate protection," "comprehensive contract," and "sufficiently" ambiguous. Therefore, this Court should disregard the proposed finding.

1079. Contrary to the opinion of Dr. Scott Morton, behavioral remedies can function effectively in innovation markets by including, as the Open Offer does, terms that can adapt to changed circumstances in evolving marketplaces. (RX6002 (Guerin-Calvert Trial Dep. at 103–04).)

Response to Finding No. 1079

The proposed finding is vague because it fails to define or describe what "function

effectively in innovation markets" means.

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry to support Respondents' proposed "fact."

[redacted]

1079.1 For example, the Open Offer's provisions on pricing for new Supplied Products or new versions of materially improved Supplied Products require that the prices are "commercially reasonable" and empower an arbitrator to evaluate the commercial reasonableness of the prices. (RX3935 (Illumina) at 2–3.)

Response to Finding No. 1079.1

The proposed finding is vague because it fails to define or describe what the terms "materially improved," "commercially reasonable," and "commercial reasonableness of the prices" mean. Additionally, nowhere in the Open Offer or its amended terms, published in the middle of trial, are these terms defined or explained. (*See* PX0064 (Illumina Open Offer agreement, Mar. 29, 2021); RX3935 at 003 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

[redacted]

[redacted]

1080. Contrary to the testimony of certain customers, the Open Offer is not about optics; it is about actually working with customers to assure them that they will not be disadvantaged after the transaction. (Berry (Illumina) Tr. 856; *see also* Fiedler (FMI) Tr. 4479.)

Response to Finding No. 1080

The proposed finding is vague because it fails to identify who these "certain customers" and what they testified to. The proposed finding is vague because it fails to define or describe what the terms "optics" and "disadvantaged" mean.

The proposed finding is incorrect and misleading because it miscites to Dr. Fiedler's testimony. [redacted]

[redacted]

[redacted]

[redacted]

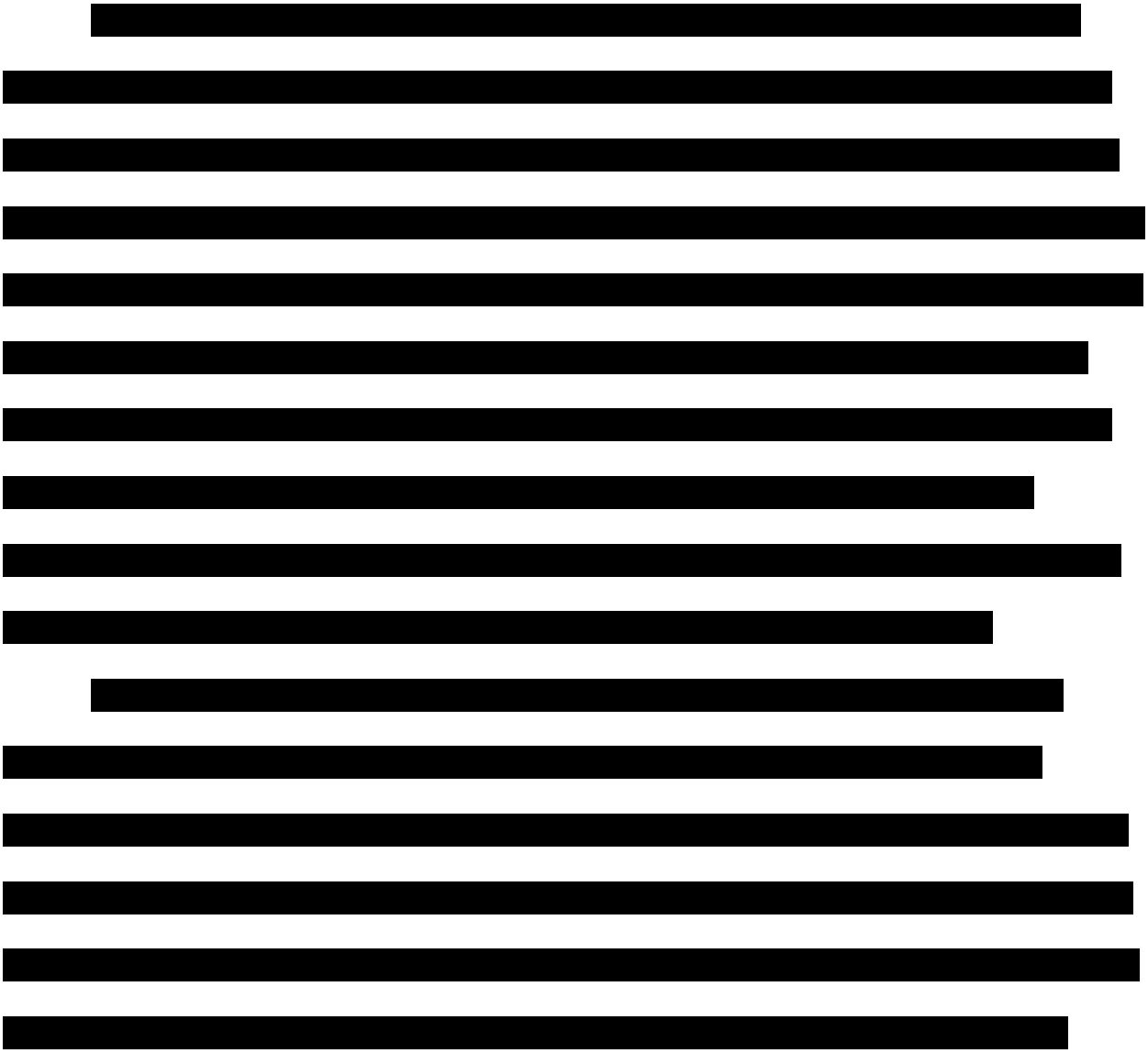
1080.1 For example, the provisions of the Open Offer came about based on what individual customers said would make them more comfortable after the Transaction. (Berry (Illumina) Tr. 857, 942–47.)

Response to Finding No. 1080.1

The proposed finding is vague because it fails to identify which "individual customers" it

refers to and what these customers said. Additionally, the proposed finding is vague because it fails to define or describe what "more comfortable" means.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents fail to cite to any customer statements supporting the "fact" that "the Open Offer came about based on what individual customers said would make them more comfortable after the Transaction.



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[redacted]

1080.2 [redacted]

Response to Finding No. 1080.2

[redacted]

[redacted]

[redacted]

1080.3 [redacted]

Response to Finding No. 1080.3

[redacted]

[redacted]

1080.4 Working with customers to ensure they are comfortable with their relationship with Illumina after the Transaction aligns with Illumina's core business strategy of creating an open platform environment to broaden the market for sequencing products. (deSouza (Illumina) Tr. 2378–82.)

Response to Finding No. 1080.4

The proposed finding is misleading to the extent it implies that Illumina cares about whether customers are comfortable with their relationship with Illumina.

[redacted]

[redacted]

[redacted]

1081. Contrary the testimony of certain customers, the reason the Open Offer provides a standardized set of terms for customers is to ensure fairness, transparency and equitable treatment for customers. (*See* Berry (Illumina) Tr. 869; Goswami (Illumina) Tr. 3206–07; [redacted] 2392, 2401, 2403.)

Response to Finding No. 1081

The proposed finding is vague because it fails to identify who these "certain customers" and what they testified to. The proposed finding is vague because it fails to define or describe what "fairness, transparency, and equitable treatment for customers" means.

[redacted]

[redacted]

[redacted]

1082. Contrary to the opinion of Dr. Scott Morton, the Open Offer fully addresses any alleged incentives by Illumina to foreclose GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 20–21, 108–09).)

Response to Finding No. 1082

[redacted]

[redacted]

[redacted]

1082.1 The most important issue with regard to the efficacy of the Open Offer is whether it sufficiently prevents Illumina from acting on any incentive to foreclose GRAIL rivals. (*See* RX6002 (Guerin-Calvert Trial Dep. at 20–21, 109).)

Response to Finding No. 1082.1

[redacted]

[redacted]

[redacted]

1082.2 Separate from Illumina's ability to foreclose, the Open Offer's provisions in their totality also ensure that Illumina's incentives are to support GRAIL's rivals. (*See* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).)

Response to Finding No. 1082.2

[redacted]

[redacted]

[redacted]

1082.3 [redacted]

Response to Finding No. 1082.3

[redacted]

[redacted]

[redacted]

1082.4 Further, the Open Offer, as a private contract, creates an incentive for Illumina customers to take advantage of it and enforce it. (RX6000 (Carlton Trial Dep. at 84).)

Response to Finding No. 1082.4

First, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Second, the proposed finding is improper, incorrect, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Carlton's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Carlton's expert opinion, in contravention of this Court's

Order, and therefore this Court should disregard Respondents' proposed finding.

The proposed finding is misleading and incorrect because the overwhelming weight of the evidence shows that neither Grail's monitors nor an independent auditor can effectively monitor Illumina's compliance with the Open Offer (CCFF ¶¶ 4843-927), and the Open Offer cannot be effectively enforced. (CCFF ¶¶ 4928-50).

The proposed finding is vague because the term "private contract" is undefined, and the term "take advantage of" if ambiguous. Additionally, the proposed finding does not specify or explain how the open offer creates an incentive for Illumina customers to take advantage of it and enforce it. Therefore, this Court should disregard the proposed finding.

> 1082.5 In addition, Complaint Counsel's expert improperly assumes that in the but-for world without the merger, Illumina has no incentive to foreclose GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 20–21, 109).) To the contrary, absent the merger, Illumina would have an incentive to favor GRAIL. (RX6000 (Carlton Trial Dep. at 45–46).) In the world absent the merger, Illumina would own roughly 12% of GRAIL, so it would make much more money by favoring GRAIL over GRAIL's rivals. (RX6000 (Carlton Trial Dep. at 45–46).)

Response to Finding No. 1082.5

First, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings).

Second, the proposed finding is improper, incorrect, and vague. The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Ms. Guerin-Calvert's and Dr. Carlton's trial deposition testimony to support the proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Ms. Guerin-Calvert's and Dr. Carlton's expert opinions, in contravention of this Court's Order, and therefore this Court should disregard

Respondents' proposed finding.

The proposed finding is incorrect because the overwhelming weight of evidence shows that pre-merger, Illumina had the incentive to promote innovation and multiple MCED tests (CCFF ¶¶ 3081-3095), while post-merger, Illumina has the financial incentive to maximize the combined profits of Illumina and Grail. (CCFF ¶¶ 3096-3106). This is confirmed by several third parties, who foresee Illumina's changed incentive as a result of the acquisition of Grail (CCFF ¶¶ 3148-3173), and Dr. Scott Morton, whose analysis of Illumina's pre- and post-merger profits demonstrates quantitatively Illumina's incentive to foreclose and raise costs to Grail's rivals. (CCFF ¶¶ 3174-3188).

The proposed finding is vague because the term "Complaint Counsel's expert" is ambiguous. Complaint Counsel had three expert witnesses: Dr. Scott-Morton, Dr. Rothman, or Dr. Navathe, and the proposed finding does not distinguish between them. Additionally, the terms "but-for world" and "much more money" are ambiguous. Therefore, this Court should disregard the proposed finding.

3. The Open Offer Addresses Any Concerns or Requests Likely to Arise During the 12–year Term

1083. Contrary to the opinions of certain customers, the Open Offer fully addresses the competitive concerns that would be likely to arise over a 12–year term. (RX6002 (Guerin-Calvert Trial Dep. at 103–04).)

Response to Finding No. 1083

The proposed finding is vague because it fails to identify who these "certain customers" and what they testified to.

[redacted]

[redacted]

1083.1 The Open Offer accomplishes this by using flexible terms that can respond to changes over time. (*See* RX6002 (Guerin-Calvert Trial Dep. at 103–04).)

Response to Finding No. 1083.1

[redacted]

[redacted]

1083.2 For example, rather than prescribing specific types of assistance, the FDA provision requires Illumina to provide whatever documentation is needed for FDA approval. (RX6002 (Guerin-Calvert Trial Dep. at 103–04).) This allows the provision to be effective even if FDA requirements change over time. (*See* RX6002 (Guerin-Calvert Trial Dep. at 104).)

Response to Finding No. 1083.2

The proposed finding relies solely upon the self-serving testing of Respondents' expert, Ms. Guerin-Calvert, and fails to cite to any customer testimony supporting this "fact."

[redacted]

[redacted]

[redacted]

1083.3 Moreover, customers have acknowledged that no contract is perfect and no contract can address all potential issues that might eventualize over the long term. (*See, e.g.*, [redacted]; Conroy (Exact/Thrive) Tr. 1723; [redacted] Nonetheless, these customers enter into contracts all the time. [redacted] Conroy (Exact/Thrive) Tr. 1723; Getty (Guardant) Tr. 2614; [redacted]

Response to Finding No. 1083.3

The proposed finding is misleading to the extent it implies that because no contract is perfect and Illumina's customers enter into imperfect contracts all the time it therefore shows that Respondents Open Offer letter is sufficient to restore the loss to competition that will take place post-acquisition. Also, the proposed finding is misleading to the extent it implies the Open Offer is a bargained-for and negotiated contract. Rather, Illumina single-handedly drafted the terms of the Open Offer and seeks to impose it onto its customers. [redacted]

[redacted]

[redacted]

4. **The Open Offer Addresses Any Concerns Relating to Access to Services**

1084. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot delay or provide lower quality technical support services in a way that would (meaningfully) affect customers. (RX6002 (Guerin-Calvert Trial Dep. at 57–59, 67).)

Response to Finding No. 1084

The proposed finding is vague because it fails to identify who these "certain customers" and what they testified to. The proposed finding is also vague because the terms "delay," "lower quality," "technical support services," and "meaningfully affect" are undefined. It is unclear from the terms of the Open Offer and this "fact" what amounts to a "delay," "lower quality," and "meaningfully." The proposed finding relies on the self-serving testimony of Respondents' own

expert, Ms. Guerin-Calvert and fails to cite to any customer testimony which supports this "fact." The proposed finding is against the weight of the evidence because it fails to take into consideration Ms. Guerin-Calvert's testimony that that an Illumina customer would not know how fast its competitors received service and support from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 151)). Also, it fails to take into account Ms. Guerin-Calvert agreement that Illumina's customers have different service contracts and different service needs and that an Illumina customer is not well positioned to compare the services it receives from Illumina with the services that its competitor receives. (RX6002 (Guerin-Calvert Trial Dep. at 151-52)).

[redacted]

[redacted]

1084.1 Illumina cannot delay technical support in a way that would affect customer's development of screening tests. (RX6002 (Guerin-Calvert Trial Dep. at 65, 67).)

Response to Finding No. 1084.1

The proposed finding is vague because it fails to define or describe what the terms "delay," "technical support," and "development" mean. It is unclear from the terms of the Open Offer and this "fact" what amounts to a "delay," "technical support," and a "customer's development of screening tests." The proposed finding relies on the self-serving testimony of Respondents' own expert, Ms. Guerin-Calvert and fails to cite to any customer testimony which supports this "fact." The proposed finding is against the weight of the evidence because it fails to take into consideration Ms. Guerin-Calvert's testimony that that an Illumina customer would not know how fast its competitors received service and support from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 151)). Also, it fails to take into account Ms. Guerin-Calvert agreement that Illumina's customers have different service contracts and different service needs and that an Illumina customer is not well positioned to compare the services it receives from Illumina with the services that its competitor receives. (RX6002 (Guerin-Calvert Trial Dep. at 151-52)).

The proposed finding is misleading to the extent it implies that customers know when their technical support is "delayed." Guardant's Mr. Getty testified that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively." (PX7105 (Getty (Guardant) Dep. at 69-71); *see* PX7105 (Getty (Guardant) Dep. at 79-80 (testifying that "ultimately we just have no ability to understand or actually enforce the terms of the contract, and such that, you know, they could continue to operate as they see fit, and ultimately over time, as we talked about, you know, change terms, change pricing, you know, send a technician a few months after they could have. Those things are unknowable and ultimately could be very debilitating to our business.")). Mr. Getty testified that Illumina's control over which MCED test developer receives better treatment makes it "very difficult" to audit how equitable Illumina's customer service is: "[T]he [Illumina] individual that was chosen to go to Guardant Health could simply have had a vacation scheduled so that seems like normal course of business. But the person who didn't have a vacation scheduled ended up at GRAIL . . . So even a third party auditor would be – it would be very difficult to gauge like-for-like in terms of services." (PX7105 (Getty (Guardant) Dep. at 85-86)).

Further, Mr. Getty testified that "there's absolutely no way to even gauge the value of that service. And so when I read things like 'service,' put it in quotes, it's a rather broad terminology. They could provide a service with a technician who, you know, just joined Illumina yesterday and has zero years of experience, and GRAIL could end up with the individual who has 25 years of experience and has been at GRAIL and worked with them ostensibly all the time. And so in short, we wouldn't know that differential, No. 1. And No. 2, if that differential exists, it conveys a very different value of service. So a term like ['Access to Service'] is largely – you

know it's – it does not convey any benefit or frankly any value to Guardant Health." (PX7105 (Getty (Guardant) Dep. 84-85)).

The proposed finding is misleading to the extent it implies that Illumina's service is not important to customers. MCED customers rely on Illumina's product and support service. (*See* CCFF ¶¶ 4511-26). The withholding of Illumina service can delay the development of MCED tests. (CCFF ¶¶ 4522, 4307). Therefore, this Court should disregard the proposed finding.

1084.2 Delaying services or providing worse services to a customer who signed the Open Offer would be a breach of the Open Offer. (Berry (Illumina) Tr. 871, 878–79.)

Response to Finding No. 1084.2

[redacted]

[redacted]

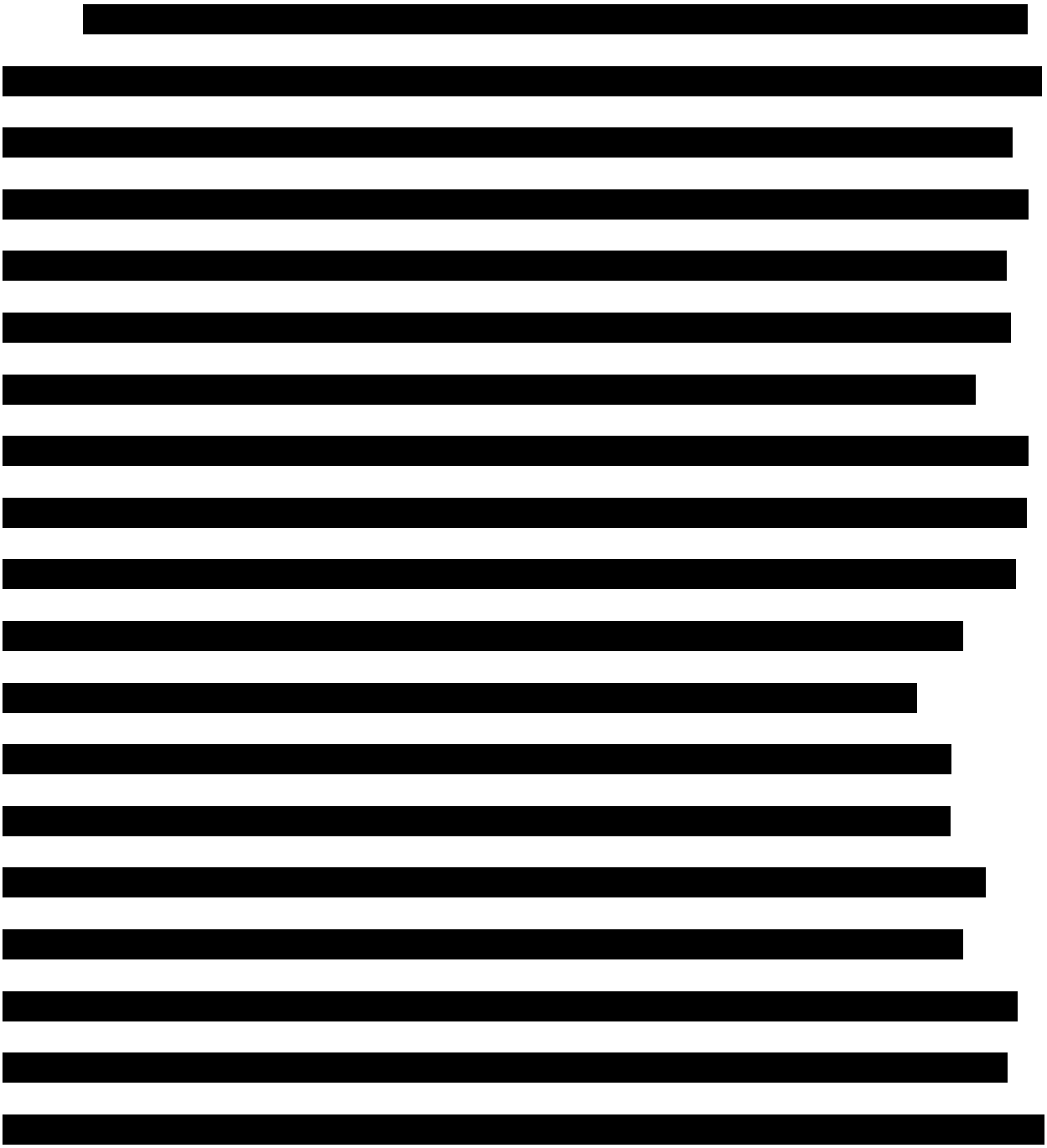
[redacted]

1084.3 Illumina tracks the services that customers order, trains technicians extensively and tracks individual cases to ensure consistent quality of services, including the speed with which the services were provided. (Berry (Illumina) Tr. 866–69.) Therefore, any deterioration in the quality of services would be verifiable through the audit provision in the Open Offer. (*See* RX6003 (Rock Trial Dep. at 59–62).)

Response to Finding No. 1084.3

The proposed finding is vague because it fails to explain what training technicians receive and what "consistent quality of services" means. Additionally, the proposed finding is vague because it fails to explain what "any deterioration in the quality of services" would entail. It is unclear whether sending an inexperienced technician or having no technicians available due

to scheduling conflicts amounts to a "deterioration in quality of services." The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry, and Respondents' own expert, Mr. Rock. Respondents fails to cite to any customer testimony in support of this "fact."



[redacted]

[redacted]

1084.4 Moreover, delaying or refusing to service instruments would hurt Illumina's overall business because customers would stop buying sequencing consumables from Illumina. (Berry (Illumina) Tr. 871–72.)

Response to Finding No. 1084.4

[redacted]

[redacted]

[redacted]

1084.5 Under the Open Offer, Illumina is prohibited from sending a deliberately inexperienced technician to address a service call at a test developer that is a GRAIL rival. (Berry (Illumina) Tr. 869.)

Response to Finding No. 1084.5

The proposed finding is vague because it fails to define or describe what is considered an "inexperienced technician" and "deliberate" behavior means. Additionally, it is unclear who gets to decide whether a technician is "inexperience" and whether Illumina's behavior is "deliberate."

[redacted]

[redacted]

[redacted]

[redacted]

1085. Contrary to the testimony of certain customers, customers will receive access to the same level of service that they received premerger. (RX6002 (Guerin-Calvert Trial Dep. at 57–58, 63).)

Response to Finding No. 1085

[redacted]

[redacted]

1085.1 The Open Offer ensures that there will not be a diminution of the sets of services available to customers relative to those available before the merger. (RX6002 (Guerin-Calvert Trial Dep. at 58).)

Response to Finding No. 1085.1

[redacted]

[redacted]

1086. Contrary to the testimony of certain customers, customers will receive access to the same level of service that GRAIL receives. (RX6002 (Guerin-Calvert Trial Dep. at 57–58, 63).)

Response to Finding No. 1086

[redacted]

[redacted]

[redacted]

1086.1 [redacted]

Response to Finding No. 1086.1

[redacted]

[redacted]

[redacted]

1086.2 Under the Open Offer, Illumina could not provide lower quality services to customers who did not also purchase Galleri. (Berry (Illumina) Tr. at 878–79.)

Response to Finding No. 1086.2

[redacted]

[redacted]

1086.3 [redacted]

Response to Finding No. 1086.3

[redacted]

[redacted]

[redacted]

1086.4 Customers will also be aware of the services provided to GRAIL because Illumina is required to publish on the "Oncology Contract Terms" website the service

plans that GRAIL purchases. (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).) Illumina is also required to update this website within 5 days of entry of any service contract by GRAIL. (RX3935 (Illumina) at 2.)

Response to Finding No. 1086.4

[redacted]

[redacted]

1086.5 The publication of the services provided to GRAIL will also assist with the audit procedure. (RX6003 (Rock Trial Dep. at 59–61).)

Response to Finding No. 1086.5

[redacted]

[redacted]

5. The Open Offer Addresses Any Concerns Relating to Access to Sequencing Instruments and Core Consumables

1087. Contrary to the testimony of certain customers, under the Open Offer, customers have access to the same sequencing instruments and core consumables as GRAIL, including any improvements or future products that Illumina may release. (Berry (Illumina) Tr. 875–76.)

Response to Finding No. 1087

[redacted]

[redacted]

[redacted]

[redacted]

1087.1 Illumina cannot define what counts as a new product for purposes of the access provisions in a way that meaningfully disadvantages GRAIL rivals because Illumina's adherence to this provision will be subject to regular audits. (RX6003 (Rock Trial Dep. at 56, 59–61).)

Response to Finding No. 1087.1

[redacted]

[redacted]

[redacted]

1087.2 To the extent Illumina introduces a new product or a new version of an existing product, "[t]he price for a new Supplied Product or a new version of a materially improved Supplied Product must be commercially reasonable. For any materially improved Supplied Product, the price of the new version must take into account the value of the improvement." (RX3935 (Illumina) at 2.)

Response to Finding No. 1087.2

[redacted]

[redacted]

1087.3 [redacted]

Response to Finding No. 1087.3

[redacted]

[redacted]

[redacted]

[redacted]

1087.4 [redacted]

Response to Finding No. 1087.4

[redacted]

[redacted]

1088. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot develop a new product that only works for GRAIL and disadvantages other test developers. (deSouza (Illumina) Tr. 2433–35.)

Response to Finding No. 1088

[redacted]

[redacted]

[redacted]

[redacted]

1088.1 Similarly, Illumina could not make improvements to its products available only to GRAIL without breaching the Open Offer. (deSouza (Illumina) Tr. 2446–47.)

Response to Finding No. 1088.1

[redacted]

[redacted]

1089. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot discontinue access to products because the no-obsolescence provision explicitly prohibits this behavior. (Rabinowitz (Natera) Tr. 421–22; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; (RX6002 (Guerin-Calvert Trial Dep. at 71–72); [redacted]

Response to Finding No. 1089

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1089.1 Under the Grandfathered Pricing provision of the Open Offer, Illumina must also allow customers to continue paying the same pre-merger price for any products that customers continue to purchase. (PX0064 (Illumina) at 7.)

Response to Finding No. 1089.1

[redacted]

[redacted]

1090. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot disadvantage GRAIL rivals by delaying access to information about new or pipeline products because the Open Offer specifically requires equitable access to information about final product specifications of new or pipeline products within 5 days of when GRAIL receives access. (deSouza (Illumina) Tr. 2407–08; RX3935 (Illumina) at 2.)

Response to Finding No. 1090

[redacted]

[redacted]

[redacted]

1090.1 Additionally, when Illumina releases a new product, customers tend to wait for a period to see how that product performs in the market before adopting it. (deSouza (Illumina) Tr. 2409.) Clinical customers typically wait a year or more to see if there are any modifications to the product and to get a sense of the product's performance characteristics. (deSouza (Illumina) Tr. 2409–10.)

Response to Finding No. 1090.1

[redacted]

[redacted]

[redacted]

1090.2 Once a customer decides to adopt a sequencing product, they typically purchase a single sequencer to validate the workflows they have and to train their employees. (deSouza (Illumina) Tr. 2410.) This validation process typically takes months or quarters. (deSouza (Illumina) Tr. 2410.) Only after this process will the customer start to roll out their product tests on the new sequencer. (deSouza (Illumina) Tr. 2410–11.)

Response to Finding No. 1090.2

[redacted]

[redacted]

1090.3 Thus, it is not uncommon for customers to adopt a new sequencer 3 or more years after the sequencer is released. (deSouza (Illumina) Tr. 2410.) For example, the NovaSeq was released in the first half of 2017, but a substantial portion of Illumina's NovaSeq customers are only now bringing the NovaSeq into their environments. (deSouza (Illumina) Tr. 2410.)

Response to Finding No. 1090.3

The proposed finding relies solely on the self-serving testimony of Illumina's CEO, Francis deSouza, and does not cite to any customer testimony to support this "fact" about customer behavior. The proposed finding is vague because it fails to define or describe what "not uncommon" means. Therefore, this Court should disregard the proposed finding.

1091. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot delay access to products in a way that would meaningfully disadvantage GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 60, 65).)

Response to Finding No. 1091

[redacted]

[redacted]

[redacted]

1091.1 The Open Offer requires that customers receive access to Supplied Products and Pre-Release Sequencing Products within 5 days of when GRAIL or Equivalent customers receive access. (RX3935 (Illumina) at 2.) [redacted]

Response to Finding No. 1091.1

[redacted]

[redacted]

[redacted]

[redacted]

1091.2 Considering the length of time that it takes to develop a test on a sequencing platform, 5 days is "a very inconsequential amount of time" for a developer making a test. (*see* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted]; PX7100 (Chudova (Guardant) Dep. at 75–79); [redacted]

Response to Finding No. 1091.2

[redacted]

[redacted]

1091.3 Customers will be aware when the "clock starts running" for the access provisions because, under the Open Offer, customers must be notified when a product is made available. (RX6002 (Guerin-Calvert Trial Dep. at 64).)

Response to Finding No. 1091.3

[redacted]

[redacted]

1091.4 Under the Open Offer, Illumina could not provide lower quality sequencing instruments or core consumables to customers who did not also purchase Galleri. (Berry (Illumina) Tr. at 879.)

Response to Finding No. 1091.4

[redacted]

[redacted]

[redacted]

1092. Contrary to the testimony of certain customers, Illumina cannot "monkey" with supply by providing customers with lower quality reagents. (RX6002 (Guerin-Calvert Trial Dep. at 62).)

Response to Finding No. 1092

[redacted]

[redacted]

1092.1 If Illumina "monkeyed" with supply by providing lower quality instruments or consumables or by delaying a purchase order, Illumina would be in breach of the Open Offer. (Berry (Illumina) Tr. 878–79.)

Response to Finding No. 1092.1

[redacted]

[redacted]

6. The Open Offer Addresses Any Concerns Relating to Pricing of Services, Sequencing Instruments or Core Consumables

1093. Contrary to the testimony of certain customers, Illumina cannot avoid its obligations under the pricing provisions by defining what counts as a material improvement or new product. (RX3935 (Illumina) at 2–3.)

Response to Finding No. 1093

[redacted]

[redacted]

[redacted]

1093.1 The Open Offer specifically prohibits price increases (other than those due to inflation or factors outside of Illumina's control) unless a new product or new version results in a material improvement. (PX0064 (Illumina) at 7.)

Response to Finding No. 1093.1

[redacted]

[redacted]

[redacted]

1093.2 Illumina's ability to raise prices based on material improvements is constrained. (RX3935 (Illumina) at 2–3.) The price of any new version must take into account the value of the improvement. (RX3935 (Illumina) at 2–3.)

Response to Finding No. 1093.2

[redacted]

[redacted]

[redacted]

[redacted]

1093.3 In any arbitration over pricing of new products or new version of products, the arbitrator "is empowered to determine the reasonableness of the price, including the value of the . . . improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer." (RX3935 (Illumina) at 2–3.)

Response to Finding No. 1093.3

The proposed finding is vague because it fails to define or describe how the arbitrator will "determine the reasonableness of the price," determine an "improvement in performance," and decide on a "price that is commensurate with the improvement." The proposed finding is vague because it fails to define or describe what is a "new product" or a "new version." Additionally, the proposed finding is misleading because nowhere in the Open Offer or its amended terms is "new product" or "new version" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021; RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). Thus, it is unclear what constitutes a new product or new version, who gets to decide this, and whether customers will be able to know when a new product or new version has occurred.

The proposed finding is misleading to the extent it implies the Open Offer's arbitrations provisions resolves customer concerns that Illumina will disadvantage Grail's rivals. MCED customers testified to their concerns regarding the Open Offer's arbitration provision. First, arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Illumina executive and Open Offer signatory, Ms. Berry, does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24). Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

An arbitration with Illumina will slow down the innovation of MCED tests. Guardant's Mr. Getty testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)). Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). FMI's Mr.

Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Ultimately, as Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)). Therefore, this Court should disregard the proposed finding.

1094. Contrary to the testimony of certain customers, the 43% price reduction by January 1, 2025 is a significant price reduction and is based on Illumina's projections with respect to the prices GRAIL would pay in 2025. (Berry (Illumina) Tr. 711–12; deSouza (Illumina) Tr. 2338; [redacted]

Response to Finding No. 1094

[redacted]

[redacted]

[redacted]

[redacted]

1094.1 In concluding that the 43% reduction was unlikely to constrain Illumina from raising prices above what they would be absent the merger, Dr. Scott Morton

improperly assumed that, in the world without the merger (1) Illumina would have succeed in sufficiently lowering its costs by 2025, (2) Illumina would have passed all of those reductions on to its customers and (3) Illumina would have provided any reductions to all customers equally. (RX6002 (Guerin-Calvert Trial Dep. at 50–52).)

Response to Finding No. 1094.1

[redacted]

[redacted]

[redacted]

1095. Contrary to the opinion of Dr. Scott Morton, charging customers the same prices as GRAIL is a meaningful pricing protection because, even though GRAIL and Illumina are affiliates, the P&L of each company will be reported separately. (deSouza (Illumina) Tr. 2465, 2467–69.)

Response to Finding No. 1095

[redacted]

[redacted]

1095.1 Indeed, GRAIL is a separate organization with its own budget. (deSouza (Illumina) Tr. 2468.) Thus, for all the items that GRAIL purchases from Illumina, GRAIL will be making a payment to Illumina. (deSouza (Illumina) Tr. 2468.)

Response to Finding No. 1095.1

[redacted]

[redacted]

[redacted]

7. The Open Offer Addresses Any Concerns Relating to IVD Agreements and FDA Documentation

1096. Contrary to the testimony of certain customers, the Open Offer's requirement that Illumina provide FDA documentation is sufficiently long to address customers' concerns with respect to FDA approval of their tests. (*See* RX6002 (Guerin-Calvert Trial Dep. at 28, 73–75).)

Response to Finding No. 1096

This Court held that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This Court should disregard this evidence.

Moreover, the proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does cite to any customer with actual experience in the industry to support Respondents' apparent "fact." Ms. Guerin-Calvert made $1,370 per hour for her work on this matter and as of one week prior to her trial deposition, had billed approximately 300 hours on this matter. (RX6002 (Guerin-Calvert Trial Dep. at 110-11)).

The proposed finding is vague because it fails to define the following terms "certain customers," "FDA documentation," and "sufficiently long." Nor are these terms defined in the Open Offer itself.

The proposed finding is misleading and vague to the extent that it does not cite to the Open Offer term which relates to the FDA. The Open Offer states that "Customer may enter into, at any time from today, effective as of the closing of the Transaction, until the sixth anniversary of the closing of the Transaction, an agreement with Illumina under which Customer may develop and commercialize in-vitro diagnostic ("IVD") test kits for use on Illumina's diagnostic ("Dx") sequencing platforms. Illumina will provide standard terms for Customer to enter into a

standalone agreement to enable Customer to develop and commercialize IVD test kits on one or all of Illumina's Dx sequencing platforms. Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test using the Supplied Products." (PX0064 (Illumina) at 006-7 (Illumina Open Offer, Mar. 29, 2021)).

Illumina customers testified at trial that the FDA related provision of the Open Offer is a concern. [redacted]

1097. Contrary to the testimony of certain customers, under the Open Offer, Illumina could not decide to withhold support or documentation for regulatory approval from a test developer that was a potential GRAIL rival. (Berry (Illumina) Tr. 915–16.)

Response to Finding No. 1097

The proposed finding is vague because it fails to define the following terms "certain customers," "support," and "documentation." Moreover, the proposed finding is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

The proposed finding is misleading to the extent that it implies Illumina cannot and has not withheld support and documentation for regulatory approval from a test developer because the developer was an Illumina competitor. [redacted]

[redacted]

8. The Open Offer Addresses Any Concerns Relating to Intellectual Property

1098. Contrary to the testimony of certain customers, the Open Offer's intellectual property provisions adequately cover both Core IP and Application Specific IP. (RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

Response to Finding No. 1098

This Court held that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert for the fact proposition of what is in the Open Offer, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This Court should disregard this evidence. Moreover, the proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does cite to any customer with actual experience in the industry to support Respondents' apparent "fact."

The proposed finding is vague because it does not define "cover," "Core IP" or "Application Specific IP." The proposed finding is also vague because it does not explain what "adequately covers" means, and it fails to identify who these "certain customers" and what they testified to.

The proposed finding is incorrect and misleading to the extent it implies that the Open Offer provides any sort of license or rights related to application-specific IP or that the provision regarding intellectual property resolves customers concerns or replaces the competitive intensity lost as a result of the merger. Illumina's Open Offer does not provide customers a right or license

to any application-specific IP, and in fact carves application-specific IP out of the Open Offer's IP protections. (*See* PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)).

[redacted]

Freenome's fear is made even more real by the fact that Illumina's arbitration provision specifically carves out intellectual property disputes allowing Illumina to entangle customers in years long legal battles even if no IP infringement is ever proven. (PX0064 at 10 (Illumina Open Offer agreement, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding.

> 1098.1 Illumina cannot cease shipping a product based solely on a claim of infringement for both Core and Application Specific IP. (RX6002 (Guerin-Calvert Trial Dep. at 78).)

Response to Finding No. 1098.1

This Court held that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert for the fact proposition of what is in the Open Offer, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This Court should disregard this evidence.

Moreover, the proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does cite to any customer with actual experience in the industry to support Respondents' apparent "fact."

The proposed finding is misleading to the extent it implies Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted]

1098.2 The Open Offer provides an additional assurance by promising customers that they will receive rights to use Illumina's Core IP. (RX6002 (Guerin-Calvert Trial Dep. at 78–79).)

Response to Finding No. 1098.2

This Court held that experts shall not be cited to "support factual proposition that should be established by fact witnesses or documents." Here Respondents cite Ms. Guerin-Calvert for the fact proposition of what is in the Open Offer, in contravention of this Court's Order. *See* Order on Post-Trial Findings at 3. This Court should disregard this evidence. Moreover, the proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does cite to any customer with actual experience in the industry to support Respondents' apparent "fact."

The proposed finding is misleading to the extent it implies the Open Offer provisions

relating to "Core IP" provides "additional assurances" to customers. The bulk of customer concerns regarding intellectual property relate to application-specific IP thus the Open Offer's promise to provide customers rights to "Core IP" does not resolve the concerns customers have regarding intellectual property. [redacted] Freenome's fear is made even more real by the fact that Illumina's arbitration provision specifically carves out intellectual property disputes allowing Illumina to entangle customers in years long legal battles even if no IP infringement is ever proven. (PX0064 at 10 (Illumina Open Offer agreement, Mar. 29, 2021)). Therefore, this Court should disregard the proposed finding.

1099. Contrary to the testimony of certain customers, Illumina does not wield its intellectual property in a non-competitive manner. (*See* deSouza (Illumina) Tr. 2470–71.)

Response to Finding No. 1099

The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza. Respondents ignore extensive evidence from Illumina's customers who view Illumina as using IP litigation aggressively to entrench its dominant market position in areas in which it competes.

The proposed finding is vague because it fails to define what "non-competitive manner" means and fails to specify which "certain customers" it is referring to. The proposed finding is also vague because it fails to identify who these "certain customers" and what they testified to.

The proposed finding is misleading and against the weight of the evidence to the extent it

implies that Illumina does not use its intellectual property in a non-competitive manner.

Illumina's competitors and customers testified that Illumina uses its intellectual property and the threat of a legal action alleging IP infringement to discipline and control its customers and competitors. [redacted] The threat of Illumina IP litigation is so evident that Natera represented to investors in its Form 10-K that "in the event that it is in our commercial or financial interest or we are forced to transition sequencing platforms … we may be unable to do so in a commercially sustainable way and that could survive claims of infringement of intellectual property rights of Illumina and other competitors in a timely manner or at all." (PX0155 at 32 (Natera, 2020 Form 10-K, Dec. 31, 2020)).

Illumina past behavior in the NIPT market shows how Illumina has welded its intellectual property in an anti-competitive manner. [redacted]

[redacted]

Illumina continues to use its intellectual property in an anti-competitive manner through its most recent suit of Guardant. Even though [redacted] after Guardant put forward two witnesses to testify at trial on behalf of the Government, Illumina sued Guardant in federal court, alleging intellectual property violations against Guardant's founders from when they were Illumina employees over nine years ago and that Illumina allegedly learned about three years ago. (*See* Complaint, Illumina, Inc. v. Guardant Health, Inc., et. al., No. 1:22-cv-00334 (D. Del. Mar. 17, 2022)).

[redacted]

[redacted]

1099.1 When Illumina has sued entities based on Illumina's intellectual property, it has done so because those entities infringed Illumina's intellectual property. (deSouza (Illumina) Tr. 2470.)

Response to Finding No. 1099.1

The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza. Respondents ignore extensive evidence from Illumina's customers who view Illumina as using IP litigation aggressively to entrench its dominant market position in areas in which it competes.

The proposed finding is also misleading to the extent it implies the only reason Illumina sues entities is because they are actually infringing on Illumina's intellectual property. Evidence shows that Illumina has sued and threatened to sue entities with accused intellectual property violations when in fact Illumina is disciplining the entity for behavior not in Illumina favor. For example, even though [redacted]

after Guardant put forward two witnesses to testify at trial on behalf of the Government, Illumina sued Guardant in federal court, alleging intellectual property violations against Guardant's founders from when they were Illumina employees over nine years ago and that Illumina allegedly learned about three years ago. (*See* Complaint, Illumina, Inc. v. Guardant Health, Inc., et. al., No. 1:22-cv-00334 (D. Del. Mar. 17, 2022)). Additionally, with regards to the NIPT market [redacted]

Therefore, this Court should disregard the proposed finding.

> 1099.2 Indeed, when Illumina sued Natera for infringement, Illumina was obligated to sue because Illumina is the custodian of a patent pool with multiple patentholders. (deSouza (Illumina) Tr. 2470–71.)

Response to Finding No. 1099.2

The proposed finding relies solely upon the self-serving testimony of Illumina's CEO,

Francis deSouza. Respondents ignore extensive evidence from Illumina's customers who view Illumina as using IP litigation aggressively to entrench its dominant market position in areas in which it competes.

The proposed finding is misleading to the extent it implies that Illumina sued or threatened to sue Natera and Natera's customers only because Illumina is the custodian of a patent pool. [redacted]

Additionally, the proposed finding is misleading to the extent it implies that Natera infringed on Illumina's intellectual property. [redacted]

[redacted]

1099.3 Illumina's efforts in creating this patent pool helped prevent the non-competitive use of intellectual property rights in the market for non-invasive prenatal tests (NIPT.) (*See* PX7089 (Naclerio (Illumina) Dep. at 49–50, 57–58, 150).)

Response to Finding No. 1099.3

The proposed finding relies solely upon the self-serving testimony of Illumina's former Senior Vice President of Corporate and Venture Development, Nick Naclerio. Respondents ignore extensive evidence from Illumina's customers who view Illumina's creation of the NIPT patent pool as a "tariff". [redacted]

The proposed finding is misleading to the extent it implies Illumina's only intent in creating the NIPT patent pool was to "help prevent the non-competitive use of intellectual property rights" in the NIPT market. [redacted]

[redacted]

1099.4 In the nascent NIPT market that existed before Illumina acquired Verinata, several companies, such as Verinata, Sequenom and Ariosa, were engaged in ongoing intellectual property litigation. (PX7089 (Naclerio (Illumina) Dep. at 49).) These disputes led to exceedingly high prices for NIPT tests for patients. (PX7089 (Naclerio (Illumina) Dep. at 49–50).) Illumina recognized that these disputes held back the NIPT market. (PX7089 (Naclerio (Illumina) Dep. at 49–50).)

Response to Finding No. 1099.4

[redacted]

[redacted]

[redacted]

1099.5 Illumina chose to acquire Verinata in part to accelerate adoption of NIPT by settling this intellectual property litigation. (PX7089 (Naclerio (Illumina) Dep. at 57–58).) Illumina recognized that it could accomplish this because Illumina could help bring the companies in disputes to the negotiating table. (PX7089 (Naclerio (Illumina) Dep. at 57–59).)

Response to Finding No. 1099.5

[redacted]

[redacted]

1099.6 Illumina's strategy in this acquisition was to settle the intellectual property litigation promptly and then make NIPT technology available to other labs around the world to grow the market and lower prices. (PX7089 (Naclerio (Illumina) Dep. at 58–59).)

Response to Finding No. 1099.6

[redacted]

[redacted]

[redacted]

1099.7 [redacted] , 150).)
[redacted] 150).)

Response to Finding No. 1099.7

[redacted]

[redacted]

[redacted]

9. The Open Offer Addresses Any Concerns Relating to Firewalls and Confidential Information

1100. Contrary to the testimony of certain customers and the opinion of Dr. Scott Morton, the GRAIL firewall can be effectively implemented and provides adequate protection for customers' confidential information. (RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

Response to Finding No. 1100

[redacted]

[redacted]

[redacted]

1100.1 Illumina is currently implementing the confidentiality provisions of the Open Offer by operating GRAIL as a completely separate and distinct organization and by thoroughly reviewing any interface points with GRAIL. (Berry (Illumina) Tr. 917–18.)

Response to Finding No. 1100.1

[redacted]

[redacted]

1100.2 The firewall under the Open Offer will have all of the necessary characteristics of an effective firewall, including clear policies around confidentiality, a means to enforce the firewall and a means to disseminate confidentiality policies to relevant personnel. (*See* RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

Response to Finding No. 1100.2

[redacted]

[redacted]

[redacted]

[redacted]

1100.3 These types of firewalls have been implemented by the FTC (and other antitrust agencies or regulatory agencies) in vertical transactions with success since at least the 1970s. (RX6002 (Guerin-Calvert Trial Dep. at 81–82); *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In re Evanston Northwestern Healthcare Corp.* Final Order) at 5–7; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4.)

Response to Finding No. 1100.3

[redacted]

[redacted]

[redacted]

[redacted]

1100.4 The Open Offer's firewall and confidentiality provisions are consistent with and provide the essential features of those used in actual consent decrees and guidelines from the American Bar Association, the ICN Merger Guides and other merger remedy guides. (RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

Response to Finding No. 1100.4

[redacted]

[redacted]

1100.5 Illumina's customers, such as FMI, have implemented firewalls in the past and have complied with their obligations. (Fiedler (FMI) Tr. 4488.) Dr. Fiedler of FMI also testified that based on historical experience, he had no reason not to trust that Illumina would comply with its firewall obligations. (Fiedler (FMI) Tr. 4487–88.)

Response to Finding No. 1100.5

[redacted]

[redacted]

[redacted]

10. **The Open Offer Addresses Any Concerns Relating to Its Enforcement Provisions**

1101. Contrary to the testimony of certain customers, audits under the Open Offer occur with sufficient regularity to ensure Illumina adheres to its obligations under the Open Offer. (Nolan (Freenome) Tr. 2844–45; RX3935 (Illumina) at 3; [redacted]

Response to Finding No. 1101

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1101.1 [redacted]

Response to Finding No. 1101.1

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1101.2 To provide customers with even greater security, the Open Offer provides for regular audits twice a year. (RX3935 (Illumina) at 3.)

Response to Finding No. 1101.2

[redacted]

[redacted]

[redacted]

1102. Contrary to the testimony of certain customers, there is no indication that the selected auditor would be biased in favor of Illumina because the Open Offer requires "an independent third-party auditor" selected "from among the 'Big 4' accounting firms". (PX0064 (Illumina) at 10.)

Response to Finding No. 1102

[redacted]

[redacted]

[redacted]

1103. Contrary to the testimony of certain customers and the opinion of Dr. Scott Morton, the provisions of the Open Offer can be audited effectively. (*See* RX6003 (Rock Trial Dep. at 50–55, 59–65, 67–71).)

Response to Finding No. 1103

The proposed finding is vague because it fails to identify who these "certain customers" and what they testified to. The proposed finding is vague because it fails to define or describe "audited effectively" means. The proposed finding solely relies on the self-serving testimony of Respondents' paid expert, Mr. Rock.

The proposed finding is misleading to the extent it implies that Illumina has determined how the auditor will function. Illumina had not engaged an auditor when Respondents' expert, Mr. Rock, prepared his expert report. (RX6003 (Rock Trial Dep. at 82)). Neither Illumina nor anyone else had determined the specific procedures that would be employed by an auditor when Mr. Rock prepared his expert report. (RX6003 (Rock Trial Dep. at 82)). The specific procedures that would be employed by an auditor had not been established when Mr. Rock prepared his expert report. (RX6003 (Rock Trial Dep. at 82)). The specific procedures that would be employed by an auditor had not been established at the time of Mr. Rock's deposition. (RX6003 (Rock Trial Dep. at 83)). Illumina executive and Open Offer signatory, Ms. Berry,

testified that the auditor may potentially have access to Illumina's service reports, but she could not confirm. (PX7076 (Berry (Illumina) Dep. at 288-89)). Ms. Berry testified that she did not believe that notes related to customer negotiations constitute "books and records" for purposes of the open offer, but she could not confirm. (PX7076 (Berry (Illumina) Dep. at 289)). Ms. Berry testified that she did not know whether a customer would have to give approval before the auditor has access to their confidential information. (PX7076 (Berry (Illumina) Dep. at 290-91)). Respondents paid expert, Ms. Guerin-Calvert, agreed that an auditor of Illumina's compliance with its commitments pursuant to the Open Offer does not determine whether Illumina violated those commitments. (RX6002 (Guerin-Calvert Trial Dep. at 132)). Therefore, this Court should disregard the proposed finding.

> 1103.1 The theory of incomplete contracting does not suggest that the audit provisions are ineffective because audit provisions in contracts can function effectively even if they (like all contracts) cannot anticipate every possible contingency. (RX6002 (Guerin-Calvert Trial Dep. at 102–04).)

Response to Finding No. 1103.1

[redacted]

[redacted]

[redacted]

1103.2 Illumina can follow several steps to ensure that the Open Offer audits are effective: (1) establish evaluation criteria, (2) develop and document systems for tracking and reporting, (3) develop a reporting framework to evaluate compliance, (4) develop an internal audit program to monitor and test compliance, (5) engage the independent auditor, (6) establish a data room to allow customers to review information on a more timely basis, (7) establish an Open Offer compliance hotline, (8) develop agreed-upon procedures to address the concerns that have been raised, (9) allow the independent auditor to perform the procedures and publish their findings and (10) engage an auditor to address alleged breaches outside of regular audits. (RX6003 (Rock Trial Dep. at 50–56).)

Response to Finding No. 1103.2

[redacted]

[redacted]

[redacted]

[redacted]

1103.3 Illumina is contractually committed to cooperating in any audits under the Open Offer. (PX0064 (Illumina) at 10.) This enhances the efficacy of the audit. (RX6002 (Guerin-Calvert Trial Dep. at 86–87).)

Response to Finding No. 1103.3

[redacted]

[redacted]

[redacted]

[redacted]

1103.4 The policies, procedures and reporting processes for an audit can be tailored to each assurance area specified in the Open Offer. (RX6003 (Rock Trial Dep. at 31).)

Response to Finding No. 1103.4

[redacted]

[redacted]

[redacted]

1103.5 An independent auditor can audit the access to services and products provisions by publishing a comprehensive catalog of services and products, issuing notices when the catalog is updated and having the auditor perform procedures to test whether the catalog is updated, accurate and timely. (RX6003 (Rock Trial Dep. at 59–62); *see also* RX6002 (Guerin-Calvert Trial Dep. at 158–161); PX7076 (Berry (Illumina) Dep. at 294).)

Response to Finding No. 1103.5

[redacted]

[redacted]

[redacted]

[redacted]

1103.6 An independent auditor can audit the pricing provisions by ensuring that the population of data audited is complete, ensuring accuracy of net prices and discount tiers and ensuring reporting and compliance with the no-price-increase commitment. (RX6003 (Rock Trial Dep. at 63–65); *see also* RX6002 (Guerin-Calvert Trial Dep. at 159); PX7076 (Berry (Illumina) Dep. at 284, 290).)

Response to Finding No. 1103.6

[redacted]

[redacted]

[redacted]

1103.7 An independent auditor can audit the confidentiality provisions by obtaining a list of Illumina employees working with GRAIL and ensuring the list is complete and accurate, obtaining a list of all Illumina and GRAIL employees who are authorized to receive confidential information, executing employee compliance certifications regularly, examining reports of violations, performing keyword email searches, creating and testing electronic barriers, testing for noncompliance with respect to hard-copy information and interviewing select personnel. (RX6003 (Rock Trial Dep. at 67–71).)

Response to Finding No. 1103.7

[redacted]

[redacted]

1104. The Open Offer adequately addresses the concern of certain customers that Illumina would get to decide whether there was a good-faith basis for requesting an additional audit because customers must be notified of any potential noncompliance with Illumina's obligations. (RX3935 (Illumina) at 2–3.)

Response to Finding No. 1104

[redacted]

[redacted]

[redacted]

[redacted]

1105. Contrary to the testimony of certain customers and the opinion of Dr. Scott Morton, the arbitration provisions of the Open Offer are not excessively costly or time-consuming. (RX6002 (Guerin-Calvert Trial Dep. at 90–92).)

Response to Finding No. 1105

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer with actual experience in the industry or any customer subject to the Open Offer to support Respondents' proposed "fact."

The proposed finding is vague because it fails to define or describe what "excessively costly or time-consuming means." Additionally, it is unclear who gets to decide whether an arbitration is "excessively costly and time-consuming." Under Illumina's Open Offer provisions an arbitration could take up to 120 days. (PX0064 at 010-11 (Illumina, Open Offer Letter, Mar. 29, 2021); *see* Berry (Illumina) Tr. 721-23)).

The proposed finding is misleading to the extent it implies that an arbitration with Illumina pursuant to the Open Offer is not costly and time consuming. MCED customers testified to their concerns regarding the Open Offer's arbitration provision. First, arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-

99); PX7105 (Getty (Guardant) Dep. at 93)). To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Illumina executive and Open Offer signatory, Ms. Berry, does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24). Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

An arbitration with Illumina will slow down the innovation of MCED tests. Guardant's Mr. Getty testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)). Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the

marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Ultimately, as Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)). Therefore, this Court should disregard the proposed finding.

> 1105.1 Customers will be willing to undertake arbitration in circumstances where it is cost-effective. (RX6002 (Guerin-Calvert Trial Dep. at 90–92).)

Response to Finding No. 1105.1

The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any customer testimony to support a "fact" about customer behavior.

The proposed finding is misleading to the extent it implies that Illumina customers will "undertake arbitration" with Illumina. MCED customers testified to Illumina being their sole

supplier of NGS and having no alternatives to switch to. (CCFF ¶¶ 1053-1200). It is unrealistic to assume that an arbitration with Illumina will be cost-effective when it could jeopardize the customer's relationship with an important supplier. Guardant's Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Mr. Fiedler testified that being in a contractual dispute with an essential supplier for FMI, such as Illumina, would be a "very grave concern if this would impact deliveries." (PX7118 (Fiedler (FMI) Dep. at 85-86) ("Q. Do you see any issues with being in a contractual dispute with an essential supplier for FMI? [Objections] A. I think the main concern is that as long as the delivery continues during that dispute, then as I said, it's the extra service of the extra flexibility that might be missing. It would be of very grave concern if this would impact deliveries.")). Therefore, this Court should disregard the proposed finding.

> 1105.2 Moreover, many steps of the arbitration process can occur in parallel. (deSouza (Illumina) Tr. 2460.) Additionally, Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (deSouza (Illumina) Tr. 2460–61.)

Response to Finding No. 1105.2

The proposed finding is vague because it fails to define or describe what "occur in parallel" means. The proposed finding relies solely upon the self-serving testimony of Illumina's CEO, Francis deSouza and fails to cite to any documentary evidence, past arbitration provisions, or customer testimony to support the claim that "Illumina aims to get through any arbitration as fast as possible…"

The proposed finding is misleading to the extent it implies that the Open Offer requires Illumina to get through an arbitration "as fast as possible." To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)). Arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). It is unclear whether Grail would have to go through the same 120-day arbitration process, so an arbitration no matter how short in length would put a customer at a disadvantage to Grail. (*See* Berry (Illumina) Tr. 723-24).

The proposed finding is misleading to the extent it implies the Open Offer's arbitrations provisions resolves customer concerns that Illumina will disadvantage Grail's rivals. MCED customers testified to their concerns regarding the Open Offer's arbitration provision. First, arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's]

time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Illumina executive and Open Offer signatory, Ms. Berry, does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24). Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

An arbitration with Illumina will slow down the innovation of MCED tests. Guardant's Mr. Getty testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)). Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Ultimately, as Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)). Therefore, this Court should disregard the proposed finding.

> 1105.3 Prior to any binding arbitration, the Open Offer also provides for an immediate dispute resolution process, which helps address any concern about the time and expense of arbitration. (PX0064 (Illumina) at 10; RX6002 (Guerin-Calvert Trial Dep. at 89–91).)

Response to Finding No. 1105.3

The proposed finding is vague because it fails to define or describe what this "immediate dispute resolution process" will entail. Additionally, it is unclear which Open Offer provision provides this "immediate dispute resolution process." The closest provision to an "immediate dispute resolution process" is the arbitration term stating: "[p]rior to submitting any matter to arbitration, Illumina and Customer shall each designate a contact having the proper authorization to resolve the Dispute in a final and binding fashion, who shall meet in person or by telephone for a period of thirty (30) days (or such other period of time as Illumina and Customer shall mutually agree) in an attempt to resolve the Dispute in good faith." (PX0064 at 10). It is unclear

whether 30 days should be considered an "immediate dispute resolution" or whether this pre-arbitration meeting will actually resolve a potential dispute.

The proposed finding is also vague because it fails to explain why the "immediate dispute resolution process" "helps address any concern about the time and expense of arbitration.

The proposed finding relies upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and fails to cite to any customer testimony supporting the claim that the Open Offer includes an "immediate dispute resolution process" that "helps address any concern about the time and expense of arbitration."

The proposed finding is misleading to the extent it implies that this "immediate dispute resolution process" resolves customers concerns regarding the time and expense of arbitration with Illumina. MCED customers testified to their concerns regarding the Open Offer's arbitration provision. First, arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)). To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

Guardant's Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)). The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)). Illumina

executive and Open Offer signatory, Ms. Berry, does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24). Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

An arbitration with Illumina will slow down the innovation of MCED tests. Guardant's Mr. Getty testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)). Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Ultimately, as Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that

relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)). FMI's Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)). Therefore, this Court should disregard the proposed finding.

VIII. THE BENEFITS OF THE TRANSACTION MORE THAN OFFSET THE ALLEGED HARM

1106. Respondents have offered unrefuted evidence that the reunion will lead to merger specific efficiencies including (1) saving of thousands of lives, (2) acceleration of market access to Galleri, (3) R&D efficiencies, (4) reduction of GRAIL's royalty burden, (5) elimination of double marginalization and (6) supply chain efficiencies, operational efficiencies and acceleration of international expansion of Galleri. (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3283–84; 3307–08; 3320–21; Della Porta (GRAIL) Tr. 538–41; Freidin (GRAIL) Tr. 2973–74, 2986, 2999, 3007–08.)

Response to Finding No. 1106

The proposed finding is disingenuously misleading, incorrect, and this Court therefore should disregard Respondents' proposed evidence. The evidence offered by Respondents with respect to efficiencies is, in fact, heavily disputed. Complaint Counsel's post-trial brief, proposed findings of fact, and reply brief clearly refute Respondents' unsubstantiated efficiencies claims and demonstrate that Respondents' efficiencies claims are not cognizable nor can they justify the likely harm to competition from the Transaction. ([redacted] A cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on

vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90.

The proposed finding is also vague. Respondents fail to define and/or quantify the terms "the reunion," "thousands," "acceleration," "market access," "R&D efficiencies," "reduction," and "international expansion." Therefore, this Court should disregard the proposed finding.

1107. While Complaint Counsel has argued that the efficiencies of the Transaction are unsubstantiated, each was supported by every Illumina and GRAIL witness to testify about them. (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3307–08, 3320–21, 3283–84; Freidin (GRAIL) Tr. 2973–74, 2986, 2999, 3007–08; Della Porta (GRAIL) Tr. 538–41; [redacted]

Response to Finding No. 1107

[redacted]

[redacted]

1108. That includes the trial testimony of Francis deSouza (President and Chief Executive Officer of Illumina), Dr. Alex Aravanis (Chief Technology Officer of Illumina and former head of R&D at GRAIL), Dr. Phil Febbo (Chief Medical Officer of Illumina), Ammar Qadan (Vice President and Global Head of Market Access at Illumina), Jay Flatley (former CEO and Chairman of the Illumina Board of Directors at the time of the Transaction), Hans Bishop (CEO of GRAIL), Dr. Joshua Ofman (President and Chief Medical Officer and then-Head of External Affairs of GRAIL), Aaron Freidin (Senior Vice President of Finance at GRAIL), Christopher Della Porta (Senior Director of Commercial Partnerships and then-Director of Growth Strategy at GRAIL) and Dr. Arash Jamshidi (then-Senior Vice President of Data Sciences at GRAIL). (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3307–08, 3320–21, 3283–84; Freidin (GRAIL) Tr. 2973–74, 2986, 2999, 3007–08; [redacted]

Response to Finding No. 1108

[redacted]

[redacted]

[redacted]

1109. Complaint Counsel either conducted no cross examination of these witnesses on the Transaction or its questioning readily affirmed the efficiencies.

Response to Finding No. 1109

The proposed finding is uncited, improper, vague, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

A cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly

sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90.

Respondents assert that "Complaint Counsel either conducted no cross examination of these witnesses on the Transaction's benefits or its questioning readily affirmed the efficiencies." Resp.'s Post-Trial Brief at 181-82. Yet, Complaint Counsel's robust cross-examinations of Respondents' witnesses, coupled with other testimony and ordinary course documents, demonstrates [redacted] Therefore, this Court should disregard the proposed finding.

1110. What is more, the former Chairman of Illumina (Jay Flatley), who is no longer affiliated with the company, testified—without contradiction—that the Illumina Board came to the unanimous conclusion that the Transaction will generate specific efficiencies, including accelerating the adoption of Galleri, streamlining the supply chain, streamlining operations, accelerating international expansion, generating R&D efficiencies and, most importantly, saving lives. (Flatley (Illumina) Tr. 4081–97.)

Response to Finding No. 1110

The proposed finding is vague and a legal conclusion, and it should be disregarded by this Court. Respondents fail to define the terms "specific efficiencies," "accelerating the adoption of Galleri," "adoption," "streamlining," "supply chain," "operations," "accelerating international expansion," "generating," and "R&D efficiencies."

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 182).

Moreover, Respondents' legal conclusion is incorrect—Respondents have not demonstrated that "the Transaction will generate specific efficiencies." In fact, a cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90. Therefore, this Court should disregard the proposed finding.

1111. At the time the Illumina Board approved the Transaction, it was comprised of a Nobel Laureate, former FDA commissioner, financial experts and experienced veterans in the biotech industry. (PX0159 (Illumina) at 9–18.)

Response to Finding No. 1111

The proposed finding is vague and should be disregarded by this Court. Respondents fail to define the terms "financial experts" and "experienced veterans."

1112. Each of the individuals came to his or her conclusion—based on a wealth of experience, that the Transaction will generate efficiencies. (Flatley (Illumina) Tr. 4081–82.)

Response to Finding No. 1112

The proposed finding is vague, a legal conclusion, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "the individuals" and "a wealth of experience."

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 182). Whether "the Transaction will generate efficiencies" is a legal decision to be made by this Court.

Moreover, Respondents' legal conclusion is incorrect—Respondents have not demonstrated that "the Transaction will generate efficiencies." In fact, a cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced

executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90. Therefore, this Court should disregard the proposed finding.

1113. Mr. Bishop, at the time CEO of GRAIL, testified that the members of the GRAIL Board also unanimously decided to be acquired by Illumina because they had determined that the transaction would result in the best outcome for patients and reduce the risks of the challenges ahead of GRAIL. (Bishop (GRAIL) Tr. 1423; 1515.)

Response to Finding No. 1113

The proposed finding is unsupported speculation, is vague, misleading, irrelevant, and contradicted by the weight of the evidence. First, Complaint Counsel objects to this proposed finding because Mr. Bishop lacks foundation to testify as to whether the Acquisition will result in any acceleration efficiencies (*i.e.*, broader of faster adoption) or international efficiencies. Mr. Bishop admitted at trial that "integration planning hasn't started" between Illumina and Grail. (Bishop (Grail) Tr. 1425). Indeed, record evidence shows [redacted]

[redacted] Therefore, Mr. Bishop lacks foundation to testify regarding any alleged efficiencies, and the proposed finding should be dismissed as unsupported speculation.

Second, the proposed finding is vague as to the terms "best outcomes," "risks", and "challenges." To the extent, the proposed finding is referring to Respondents' acceleration efficiencies, the proposed finding is misleading and contradicted by the weight of the evidence. *See* Complaint Counsel's Post-Trial Reply Brief § V.B.

Third, to the extent the proposed finding implies that Grail did not have options apart from a merger with Illumina to secure additional financing, the proposed finding is misleading and contradicted by the weight of the evidence. For example, prior to the Acquisition, [redacted]

[redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1114. The GRAIL board had deep experience in contemplating the different paths ahead and had done so multiple times with different companies; and employed the advice of expert advisors. (Bishop (GRAIL) Tr. 1422.)

Response to Finding No. 1114

The proposed finding is vague, incomplete, and misleading. The proposed finding is vague because it states that board has "deep experience" but does not specify what type of experience the board possessed, or whether (and if so, how) such experience was relevant to analysis of the Acquisition. The proposed finding also is vague as to the phrase "multiple times with different companies" as it is unclear how many times, and which companies, the board had alleged experience with. Similarly, the phrase "different paths" is vague because it is not clear what paths the board considered for Grail according to this finding. Finally, "expert advisors" is vague because it is unclear how many, and what type, of alleged expert advisors were retained.

The proposed finding is incomplete and misleading to the extent it implies that that Grail

board did not seriously consider an IPO at the same time as it considered the Acquisition. Record evidence demonstrates that as [redacted] In its S-1 filings with the SEC, Grail explained that funds raised through the IPO would fund its research, facilitate market access, and scale Grail's technology and lab operations. (CCFF ¶ 5895). Through a series of [redacted]

Finally, the proposed finding is misleading to the extent it implies [redacted] Therefore, the proposed finding should be disregarded.

1115. [redacted]

Response to Finding No. 1115

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1116. On the flip side, Complaint Counsel offered no fact evidence—not a single witness—to say otherwise. The proof of efficiencies was conclusive.

Response to Finding No. 1116

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is also confusing. Respondents mistakenly represent that witnesses at trial are the only form of "fact evidence."

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Indeed, Respondents even claim their "proof" was "conclusive." Respondents have merely recited a portion of their own Post-Trial Brief—in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 182).

Moreover, Respondents' legal conclusion is incorrect—Respondents have not demonstrated that "[t]he proof of efficiencies was conclusive." In fact, a cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their

burden of demonstrating their efficiency claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90. Therefore, this Court should disregard the proposed finding.

A. The Reunion of Illumina and GRAIL Will Save Lives

1117. It is undisputed that accelerating consumer access to Galleri will save lives.

Response to Finding No. 1117

The proposed finding is uncited, improper, vague, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order. The proposed finding is also vague, as Respondents fail to define the terms "accelerating" or "consumer access." Therefore, this Court should disregard the

proposed finding.

1117.1 All agree that cancer screening saves lives. (*See* Conroy (Exact/Thrive) Tr. 1737; [redacted]

Response to Finding No. 1117.1

[redacted]

1117.2 All agree that accelerating the adoption of a cancer screening test will save more lives. (*See e.g.* Conroy (Exact/Thrive) Tr. 1739; Chahine (Helio) Tr. 1132–33; [redacted] Fiedler (FMI) Tr. 4474.)

Response to Finding No. 1117.2

[redacted]

[redacted]

1117.3 The unrefuted evidence shows that reuniting Illumina and GRAIL will accelerate the adoption of the Galleri test. (*See e.g.* deSouza (Illumina) Tr. 2411; [redacted]

Response to Finding No. 1117.3

[redacted]

[redacted]

1118. Cancer kills about 600,000 people annually in the U.S. alone and more than 9.5 million lives annually worldwide. (RX3030 (ACS) at 3, 55); RX3103 (CDC) at 1; RX3869 (Cote Expert Report) ¶ 25; CC Pre-Trial Br. at 1.)

Response to Finding No. 1118

Complaint Counsel has no specific response to this proposed finding.

1119. Cancer screening will save lives. (Conroy (Exact/Thrive) Tr. 1737; [redacted]

Response to Finding No. 1119

Complaint Counsel has no specific response to this proposed finding.

1119.1 Numerous fact witnesses, including those called by Complaint Counsel, testified that cancer screening will reduce these numbers and save lives. (Conroy (Exact/Thrive) Tr. 1737 ("Q. The widespread adoption, sir, of an MCED test, a multicancer early detection test, will save lives. Do you agree with that? A. I do agree with that."); [redacted]

[redacted]

Response to Finding No. 1119.1

[redacted]

1119.2 Complaint Counsel agrees that cancer screening save lives. (Complaint Counsel Opening Statement, Tr. 11 ("[W]e agree that the technology at issue here, MCED tests, will save lives"); Compl. ¶ 2.)

Response to Finding No. 1119.2

Complaint Counsel has no specific response to this proposed finding.

1120. Accelerating the adoption of a screening test like Galleri will save still more lives. (Conroy (Exact/Thrive) Tr. 1739; *see also* Chahine (Helio) Tr. 1132–33; Nolan (Freenome) Tr. 2725; [redacted] Fiedler (FMI) Tr. 4474.)

Response to Finding No. 1120

[redacted]

[redacted]

1120.1 Every fact witness to address the issue, including witnesses called by Complaint Counsel, testified that accelerating the adoption of a cancer screening test will save lives. For example, Kevin Conroy, the CEO of Exact Sciences, said that "the acceleration of any [cancer screening] test will save lives". (Conroy (Exact/Thrive) Tr. 1739; *see also* Chahine (Helio) Tr. 1132–33; Nolan (Freenome) Tr. 2725; [redacted] Fiedler (FMI) Tr. 4474 ("Q. And will the acceleration of a multicancer screening test on the market save lives? A. Yes, it will.").) Complaint Counsel's lead economist agreed. [redacted] *see also* PX7139 (Navathe Trial Dep. at 136 ("Q. If more Galleri tests are conducted, more cancers will be found at earlier stages; right? A. I think as a hypothetical, holding all other factors constant, yes. Q. And that would be better for

patient outcomes; right? A. Yes. Q. It will – specifically, it will extend patients' lives right? A. Yes.")).)

Response to Finding No. 1120.1

[redacted]

1120.2 The parties' experts agree that accelerating the widespread adoption of a screening test like Galleri will save more lives. (Carlton, Tr. 58–62, 72–79; [redacted]

Response to Finding No. 1120.2

[redacted]

[redacted]

1120.3 Complaint Counsel does not dispute that accelerating the adoption of a screening test like Galleri will save even more lives. (*See* Complaint Counsel Opening Statement, Tr. 11.)

Response to Finding No. 1120.3

Respondents' proposed finding is misleading, vague, misstates Complaint Counsel, and should be rejected by this Court. In the cited portion of the transcript, Complaint Counsel said "we agree that . . . MCED tests[] will save lives." (Complaint Counsel Opening Statement, Tr. 11). Complaint Counsel did not say anything about whether "accelerating the adoption of a screening test like Galleri will save even more lives." Moreover, Respondents' proposed finding is vague. Respondents fail to define the terms "accelerating," "adoption," "a screening test like Galleri," and "even more lives." Respondents disingenuously misstate Complaint Counsel and the proposed finding is otherwise vague; this Court should therefore disregard Respondents' proposed evidence. Therefore, this Court should disregard the proposed finding.

[redacted]

[redacted]

1121. The Transaction will accelerate Galleri and thus save lives. (*See e.g.* deSouza (Illumina) Tr. 2411.)

Response to Finding No. 1121

The proposed finding is vague, unsupported, misleading, and against the weight of the evidence, and this Court should disregard Respondents proposed "factual proposition." The proposed finding is vague because, as they have done throughout this litigation, Respondents fail to define the term "accelerate."

And, rather than referencing pre-acquisition, ordinary course documents for such a sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Lastly, the proposed finding is misleading and against the weight of the evidence, which shows that [redacted] More to the point, Respondents, in this proposed finding and throughout this litigation, have not provided sufficient information to verify the claim that "[t]he Transaction will accelerate Galleri," nor have they demonstrated that such a claim is merger-specific. A cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies

that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90.

[redacted]

The acceleration claims also appear inconsistent with Illumina's valuation of its Contingent Value Rights ("CVRs"), which Illumina issued when it consummated its acquisition of Grail. CVRs are similar to a royalty and entitle holders to a [redacted]

[redacted] In Illumina's Q3 2021 Quarterly Report, which its CEO reviewed and certified pursuant to Sarbanes-Oxley, Illumina valued the CVR consideration as of the Acquisition's August 18, 2021, close date at only $1.621 million. (PX0408 (Illumina) at -018 (Illumina Form 10-Q, October 3, 2021)) (measuring the $762 million CVR valuation as of the acquisition's August 18, 2021 close date); (PX0377 (Illumina) at -002 (Illumina Press Release, August 26, 2021) (announcing that "[h]olders of approximately 47% of GRAIL equity interests … elected to receive the CVR consideration," and thus, had 100% of Grail's equity holders elected to receive the CVR consideration, Illumina's 10-Q would have valued the total CVR consideration at approximately $1,621 million (of which 47% is $762 million)). [redacted]

Therefore, this Court should disregard the proposed finding.

1121.1 Illumina and GRAIL witnesses testified—without refutation—that the reunion of Illumina and GRAIL will accelerate Galleri and save lives in the U.S. and worldwide. (deSouza (Illumina) Tr. 2411; Aravanis (Illumina) Tr. 1942; Febbo (Illumina) Tr. 4327; Flatley (Illumina) Tr. 4089; [redacted] Ofman (GRAIL) Tr. 3283, 3309; Freidin (GRAIL) Tr. 2999; [redacted] *see also* Compl. ¶ 2.)

Response to Finding No. 1121.1

[redacted]

[redacted]

[redacted]

[redacted]

1121.2 Francis deSouza, Illumina's President and Chief Executive Officer, testified that "[t]his transaction has the potential to fundamentally dent the mortality curve in cancer and save many, many thousands of lives around the world. Illumina can accelerate global access to this life-saving test by making this test more available." (deSouza (Illumina) Tr. 2411.)

Response to Finding No. 1121.2

The proposed finding is misleading, against the weight of the evidence, unsupported, and vague; this Court should therefore disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence, insofar as it implies that the Transaction will "accelerate" Grail. Respondents have failed to demonstrate that "Illumina can accelerate global access" to Galleri. A cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*,

833 F. Supp. 2d at 90.

[redacted]

And, rather than referencing pre-acquisition, ordinary course documents for such a sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Lastly, the proposed finding is vague. Respondents fail to define and/or quantify the terms "potential," "fundamentally dent," "many, many thousands," "accelerate," "global access" and "more available." Therefore, this Court should disregard the proposed finding.

> 1121.3 Dr. Aravanis, Chief Technology Officer of Illumina and former head of R&D at GRAIL, testified that the Transaction "will lead to millions of more tests performed, tens of thousands of additional lives saved, reduction in the cost of the Galleri test, much broader access". (Aravanis (Illumina) Tr. 1942.)

Response to Finding No. 1121.3

The proposed finding is misleading, against the weight of the evidence, unsupported, and vague; this Court should therefore disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence. Respondents have failed to demonstrate that "the Transaction 'will lead to millions of more tests performed, tens of thousands of additional lives saved, reduction in the cost of the Galleri test, [and] much broader

access.'" A cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90.

And, rather than referencing pre-acquisition, ordinary course documents for such a sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is vague. Respondents fail to define and/or quantify the terms "millions of more tests," "tens of thousands," "reduction in the cost of the Galleri test," and "much broader access." In particular, Respondents do not indicate whether "the cost" discussed is the cost to Illumina, to Grail, or to consumers.

[redacted]

Therefore, this Court should disregard the proposed finding.

> 1121.4 Dr. Febbo, Chief Medical Officer of Illumina, testified that he recommended the approval of the Transaction because "earlier detection has the opportunity to save a lot of lives, and when I started looking at the work we were doing, it became very clear to me that Illumina reacquiring GRAIL, bringing GRAIL back into Illumina could accelerate the speed with which patients would have access to that test through multiple activities." (Febbo (Illumina) Tr. 4327.)

Response to Finding No. 1121.4

The proposed finding is misleading, against the weight of the evidence, unsupported, and vague; this Court should therefore disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence. Respondents have failed to demonstrate that "Illumina reacquiring GRAIL, bringing GRAIL back into Illumina could accelerate the speed with which patients would have access to that test through multiple activities." A cursory examination of the cited support for Respondents' efficiency claims shows that Respondents have failed to satisfy their burden of demonstrating their efficiency claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means

the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90.

And, rather than referencing pre-acquisition, ordinary course documents for such a sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is vague. Respondents fail to define and/or quantify the terms "earlier detection," "opportunity," "very clear," "could accelerate," "access," and "multiple activities."

[redacted]

Therefore, this Court should disregard the proposed finding.

1121.5 Jay Flatley, the Chairman of the Illumina Board of Directors at the time of the Transaction, testified that "[t]he board's collective judgment, as we took a final

> unanimous vote on this, was that not only was this in the interest of our shareholders but that for all the reasons I just discussed, this would have a dramatic impact on the rate with which we could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer". (Flatley (Illumina) Tr. 4089.)

Response to Finding No. 1121.5

The proposed finding is misleading, against the weight of the evidence, unsupported, and vague; this Court should therefore disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence. Respondents have failed to demonstrate that the Transaction "would have a dramatic impact on the rate with which we [Illumina] could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer." A cursory examination of the cited support for Respondents' efficiency claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90.

And, rather than referencing pre-acquisition, ordinary course documents for such a

sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is vague. Respondents fail to define and/or quantify the terms "the reasons I just discussed," "dramatic impact," and "the rate with which we could deploy the Galleri test." Importantly, Respondents fail to define the term "we" in the latter phrase, leaving it unclear whether that phrase refers to the Illumina board, or someone else.

[redacted]

Therefore, this Court should disregard the proposed finding.

1121.6 [redacted]

Response to Finding No. 1121.6

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1121.7 [redacted]

[redacted]

Response to Finding No. 1121.7

[redacted]

[redacted]

[redacted]

[redacted]}

1121.8 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that acceleration of Galleri by Illumina means that GRAIL "will do it faster. We will save more lives." (Freidin (GRAIL) Tr. 2999.)

Response to Finding No. 1121.8

The proposed finding is misleading, against the weight of the evidence, unsupported, and vague; this Court should therefore disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence. Respondents have failed to demonstrate that the Transaction will lead to "acceleration of Galleri by Illumina." A cursory examination of the cited support for Respondents' efficiency claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90.

And, rather than referencing pre-acquisition, ordinary course documents for such a sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of a Grail executive, which is uncorroborated by any ordinary course documents or analysis.

Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

For similar reasons, the proposed finding is unreliable, as Mr. Freidin lacks foundation to offer facts regarding what Illumina "will do." Mr. Freidin has never worked at Illumina, and he [redacted]

The proposed finding is vague. Respondents fail to define and/or quantify the terms "acceleration," "it," "faster," and "more." Therefore, this Court should disregard the proposed finding.

1121.9 [redacted]

Response to Finding No. 1121.9

[redacted]

[redacted]

[redacted]

1121.10 The parties' experts testified that the reunion of Illumina and GRAIL will accelerate the widespread adoption of the Galleri test. (RX6000 (Carlton, Trial Dep. at 58–62, 72–79; RX6001 (Deverka Trial Dep. at 62–64).)

Response to Finding No. 1121.10

The proposed finding is misleading. In this case, Dr. Carlton did not express an opinion regarding whether or not "the reunion of Illumina and GRAIL will accelerate the widespread adoption of Galleri." In fact, in his trial deposition, he testified that he is "relying on others" for the "opinion that Illumina will accelerate FDA approval of Galleri by at least one year." (RX6000 (Carlton Trial Dep. at 96-97)). [redacted]

[redacted] In Respondents' own words, they offer Dr. Deverka "as an expert concerning the evidence requirements to support payer decision-making for new genomics-based technologies, including how companies can drive development of such evidence and accelerate market access for new genomics-based technologies." (RX6001 (Deverka Trial Dep. at 25)). Any opinion from Dr. Deverka regarding the alleged acceleration of FDA approval for Galleri is clearly outside her expertise and outside the scope for which Respondents' offer her, and, insofar as such an opinion is implicated in this finding about "widespread adoption," it is improper.

The proposed finding is also confusing. Respondents' proposed finding concerns "[t]he parties' experts." This phrasing is confusing for two reasons. It is unclear if Respondents refer to themselves—i.e., Illumina and Grail—as "the parties," or if they are referring to the parties in this case. If the latter is true, this finding is wholly incorrect, as Complaint Counsel's experts did not testify that "the reunion of Illumina and GRAIL will accelerate the widespread adoption of the Galleri test." Second, the proposed finding is confusing because, absent the improper citation to Dr. Carlton, only one of Respondents' experts testified to the finding's claim—Dr. Deverka—leaving the whole finding incorrect for that reason alone.

Respondents' finding is vague. Respondents fail to define the terms "accelerate" and "widespread adoption." And, as discussed above, Respondents do not define what is meant by the term "[t]he parties."

[redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

1121.11 Complaint Counsel has conceded, at least implicitly, that accelerating the reunion of Illumina and GRAIL will accelerate adoption of the Galleri test. (Complaint Counsel Opening Statement, Tr. 11; [redacted]

Response to Finding No. 1121.11

This proposed finding is false and disingenuously misleading. In the cited portion of the trail transcript, Complaint Counsel stated, "we agree that the technology at issue here, MCED tests, will save lives." (Complaint Counsel Opening Statement, Tr. 11). It is no wonder Respondents do not provide the actual quotation. Nowhere in this statement does Complaint Counsel concede—neither explicitly nor "at least implicitly"—that the Transaction "will accelerate adoption of the Galleri test." [redacted] Nowhere does Dr. Scott Morton "at least implicitly" concede that the merger of Illumina and Grail will accelerate the adoption of the Galleri test. Respondents' brazen and disingenuous mischaracterization of

Complaint Counsel's statements and Dr. Scott Morton's testimony should be wholly disregarded by this Court. And just to be sure, the proposed finding is also vague. Respondents fail to define the terms "at least implicitly," "accelerating the reunion," "accelerate," and "adoption." Therefore, this Court should disregard the proposed finding.

1122. The Transaction is estimated to accelerate the adoption of Galleri by at least one year. (*See e.g.* Febbo (Illumina) Tr. 4360.)

Response to Finding No. 1122

The proposed finding is unreliable, misleading, against the weight of the evidence, and vague, and this Court should reject Respondents' proposed finding. The proposed finding is unreliable. There is no ordinary course, pre-acquisition evidence corroborating this finding's claim. And, rather than referencing pre-acquisition, ordinary course documents for such a sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is further misleading, insofar as it assumes Illumina has any ability to help Grail navigate the FDA or payer adoption processes whatsoever. [redacted]

The proposed finding is vague. Respondents fail to define the term "is estimated," "accelerate," and "the adoption." Importantly, it is totally unclear *who* has "estimated" the claim in this finding, as it is uncorroborated by any ordinary course documents and otherwise unclear

from the finding. Similarly, it remains unclear what Respondents mean by "adoption"—e.g., whether this refers to FDA approval, payer adoption, completely addressing Galleri's total market, etc. Respondents here, and elsewhere, fail to make it clear what is meant by "adoption." Therefore, this Court should disregard the proposed finding.

The acceleration claims also appear inconsistent with Illumina's valuation of its Contingent Value Rights ("CVRs"), which Illumina issued when it consummated its acquisition of Grail. CVRs are similar to a royalty and entitle holders to a [redacted] In Illumina's Q3 2021 Quarterly Report, which its CEO reviewed and certified pursuant to Sarbanes-Oxley, Illumina valued the CVR consideration as of the Acquisition's August 18, 2021, close date at only $1.621 million. (PX0408 (Illumina) at -018 (Illumina Form 10-Q, October 3, 2021)) (measuring the $762 million CVR valuation as of the acquisition's August 18, 2021 close date); (PX0377 (Illumina) at -002 (Illumina Press Release, August 26, 2021) (announcing that "[h]olders of approximately 47% of GRAIL equity interests … elected to receive the CVR consideration," and thus, had 100% of Grail's equity holders elected to receive the CVR consideration, Illumina's 10-Q would have valued the total CVR consideration at approximately $1,621 million (of which 47% is $762 million)). [redacted]

> 1122.1 Although it is difficult to quantify the extent to which the Transaction will accelerate the adoption of Galleri, Illumina has estimated that a reunited Illumina and GRAIL will accelerate Galleri's adoption by at least one year. (Febbo (Illumina) Tr. 4360 ("We determined that, in aggregate, these efficiencies will accelerate the adoption

and availability of the Galleri test by approximately at least one year."); PX7073 (Aravanis (Illumina) IHT at 77) ("We conservatively estimate that the combined benefits would be at least a year of acceleration in the overall rate of test adoption that we had in the deal model absent these efficiencies."); PX6066 (Illumina) at 8 ("Illumina expects that, as a result of the efficiencies summarized above, after the Proposed Transaction, it will be able to accelerate Galleri reaching patients at scale by at least one year."); PX2613 (Illumina) (applying an acceleration of one year to calculate lives saved).)

Response to Finding No. 1122.1

The proposed finding is unreliable, misleading, against the weight of the evidence, and vague, and this Court should reject Respondents' proposed finding. The proposed finding is unreliable. There is no ordinary course, pre-acquisition evidence corroborating this finding's claim. PX6066 is not an ordinary course document, but rather a document prepared for Dr. Aravanis in anticipation of his deposition in this case. And, rather than referencing any other pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of two Illumina executives, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executives' base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading, insofar as it assumes Illumina has any ability to help Grail navigate the FDA or payer adoption processes whatsoever. [redacted]

The proposed finding is vague. Respondents fail to define the term "difficult to quantify," "accelerate," "the adoption," and "at least one year." Importantly, it is totally unclear *who* has "estimated" the claim in this finding, as Respondents claim it is "Illumina," but the

finding is uncorroborated by any ordinary course documents. Similarly, it remains unclear what Respondents mean by "adoption"—e.g., whether this refers to FDA approval, payer adoption, completely addressing Galleri's total market, etc. Respondents here, and elsewhere, fail to make it clear what is meant by "adoption."

The testimony cited by Respondents is similarly unclear. Dr. Febbo testified that "these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year." (Febbo, Tr. at 4360). It is unclear from Dr. Febbo's testimony whether Illumina anticipates accelerating both "the adoption" and "the availability" of Galleri by a year. The latter is confusing, as Galleri is already available, in which case it is unclear what Dr. Febbo meant by "the availability." Dr. Aravanis's testimony is similarly confusing. He testified: "We conservatively estimate that the combined benefits would be at least a year of acceleration in the overall rate of test adoption that we had in the deal model absent these efficiencies." It's unclear what he meant by "conservatively estimate," "combined benefits," and "the overall rate of test adoption."

The acceleration claims also appear inconsistent with Illumina's valuation of its Contingent Value Rights ("CVRs"), which Illumina issued when it consummated its acquisition of Grail. CVRs are similar to a royalty and entitle holders to a [redacted] In Illumina's Q3 2021 Quarterly Report, which its CEO reviewed and certified pursuant to Sarbanes-Oxley, Illumina valued the CVR consideration as of the Acquisition's August 18, 2021, close date at only $1.621 million. (PX0408 (Illumina) at -018 (Illumina Form 10-Q, October 3, 2021)) (measuring the $762 million CVR valuation as of

the acquisition's August 18, 2021 close date); (PX0377 (Illumina) at -002 (Illumina Press Release, August 26, 2021) (announcing that "[h]olders of approximately 47% of GRAIL equity interests … elected to receive the CVR consideration," and thus, had 100% of Grail's equity holders elected to receive the CVR consideration, Illumina's 10-Q would have valued the total CVR consideration at approximately $1,621 million (of which 47% is $762 million)).

Therefore, this Court should disregard the proposed finding.

1122.2

Response to Finding No. 1122.2

Whether "Complaint Counsel failed to undermine" Respondent's testimony is an issue for this Court to decide and is clearly not a fact. This Court should disregard this proposed finding for that reason alone. The proposed finding is also confusing, as one does not "cross examine" testimony, but rather a witness or witnesses. Respondents confusingly believe that the only way to undermine testimony is through cross examination.

[redacted]

The acceleration claims also appear inconsistent with Illumina's valuation of its Contingent Value Rights ("CVRs"), which Illumina issued when it consummated its acquisition of Grail. CVRs are similar to a royalty and entitle holders to a [redacted] In Illumina's Q3 2021 Quarterly Report, which its CEO reviewed and certified pursuant to Sarbanes-Oxley, Illumina valued the CVR consideration as of the Acquisition's August 18, 2021, close date at only $1.621 million. (PX0408 (Illumina) at -018 (Illumina Form 10-Q, October 3, 2021)) (measuring the $762 million CVR valuation as of the acquisition's August 18, 2021 close date); (PX0377 (Illumina) at -002 (Illumina Press Release, August 26, 2021) (announcing that "[h]olders of approximately 47% of GRAIL equity interests … elected to receive the CVR consideration," and thus, had 100% of Grail's equity holders elected to receive the CVR consideration, Illumina's 10-Q would have valued the total CVR consideration at approximately $1,621 million (of which 47% is $762 million)). This implied 10-Q valuation of $1,621 million [redacted]

Therefore, this Court should disregard the proposed finding.

1123. The lives saved by the Transaction are valued at no less than $37 billion. (*See* RX6000 (Carlton Trial Dep. at 73–75).)

Response to Finding No. 1123

The proposed finding is misleading, improper, and should be rejected by this Court. The proposed finding is misleading, in that it assumes the Transaction will "accelerate the adoption

of Galleri" by one year, thereby resulting in "lives saved."

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Carlton's trial deposition testimony to support this proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Carlton's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

[redacted]

[redacted]

1123.1 Acknowledging the difficulty of valuing human life in monetary terms but using valuations routinely used by the government, Dr. Dennis Carlton (a professor of economics at the University of Chicago Booth School of Business and former Deputy Assistant Attorney General for Economic Analysis, Antitrust Division at the Department of Justice) testified that the value of an acceleration of one year is at least $37 billion. (RX6000 (Carlton Trial Dep. at 73–75).)

Response to Finding No. 1123.1

The proposed finding is misleading, vague, and should be rejected by this Court. The proposed finding is misleading, in that it assumes the Transaction will "accelerate the adoption of Galleri" by one year, thereby resulting in "lives saved." [redacted]

The proposed finding is also vague. Respondents fail to define the term "an acceleration of one year." Respondents do not indicate if this concerns their claims regarding regulatory acceleration, "market access" acceleration, international acceleration, or something else entirely. The proposed finding is unclear about which "acceleration" it discusses, and this Court should therefore disregard it as vague.

[redacted]

[redacted]

[redacted]

1123.2 Dr. Carlton estimated that a one-year acceleration would lead to an additional 10 million tests performed in the U.S. over a nine-year period (2022–2030). (RX6000 (Carlton Trial Dep. at 73–75); [redacted]

Response to Finding No. 1123.2

The proposed finding is misleading, in that it assumes the Transaction will "accelerate the adoption of Galleri" by one year, thereby resulting in "lives saved." [redacted]

The proposed finding is also vague. Respondents fail to define the term "a one-year acceleration." Respondents do not indicate if this concerns their claims regarding regulatory acceleration, "market access" acceleration, international acceleration, or something else entirely. The proposed finding is unclear about which "acceleration" it discusses.

[redacted]

[redacted]

[redacted]

1123.3 As shown in the chart below, Dr. Carlton then used "estimates in the literature about how Galleri testing will save lives" and arrived at a "range . . . from 7,429 to 10,441" lives saved from the acceleration. (RX6000 (Carlton Trial Dep. at 73–75); [redacted]

Table 11

Table 3: Baseline tests projected in deal model and impact of one-year acceleration in U.S.

Year	Standalone Tests Sold (Million)	Accelerated Tests Sold (Million)	Additional Tests Sold (Million)	Lives Saved (74 per 100k Tests)	Lives Saved (104 per 100k Tests)
2022	0.1	0.1	0.0	30	43
2023	0.1	0.4	0.3	188	265
2024	0.4	0.9	0.5	374	525
2025	0.9	2.1	1.2	897	1,261
2026	2.1	3.7	1.6	1,207	1,696
2027	3.7	6.1	2.4	1,744	2,451
2028	6.1	7.6	1.5	1,109	1,558
2029	7.6	8.8	1.2	872	1,226
2030	8.8	10.1	1.4	1,007	1,416
Total	**29.9**	**40.0**	**10.0**	**7,429**	**10,441**

Source: Deal Model; Hubbell, et al.

(RX3864 (Carlton Expert Report) ¶ 119, Table 3.)

Response to Finding No. 1123.3

The proposed finding is misleading, in that it assumes the Transaction will "accelerate the adoption of Galleri" by one year, thereby resulting in "lives saved." [redacted]

The proposed finding is vague. Respondents fail to define the terms "used," "estimates in the literature," and "arrived at." The proposed finding is also vague because Respondents fail to define the term "the acceleration." Respondents do not indicate if this concerns their claims regarding regulatory acceleration, "market access" acceleration, international acceleration, or something else entirely. The proposed finding is unclear about which "acceleration" it discusses.

[redacted]

[redacted]

[redacted]

1123.4 Using a low estimate of $5 million for the value of lives saved, Dr. Carlton estimated a low end value of the efficiencies of $37 billion. (RX6000 (Carlton Trial Dep. at 74) ("I use $5 million, and I use the lower estimate of lives saved, what will I get? And the answer is you get $37 billion."); RX3864 (Carlton Expert Report) ¶ 120.)

Response to Finding No. 1123.4

The proposed finding is misleading, against the weight of the evidence, vague, and confusing; this Court should therefore disregard Respondents' proposed evidence. The proposed finding is misleading, in that it assumes the Transaction will "accelerate the adoption of Galleri" by one year, thereby resulting in "lives saved." [redacted]

The proposed finding is also vague. Respondents fail to define the terms "a low estimate," "a low end value," and "the efficiencies." [redacted]. This is not an estimate of "the efficiencies."

[redacted]

[redacted]

[redacted]

1124. Dr. Carlton's estimate of the value of lives saves is conservative. (RX6000 (Carlton Trial Dep. at 74).)

Response to Finding No. 1124

The proposed finding is vague and should be rejected by this Court. Respondents fail to define the term "conservative." Moreover, Respondents fail to provide any evidence that Dr. Carlton's estimate is "conservative," except for Dr. Carlton's own self-serving testimony.

[redacted]

[redacted]

[redacted]

1124.1 For example, the estimate uses the lower end of lives saved and the value of lives saved. Using the higher estimate of lives saved results in a value of over $100 billion. (RX 6000 (Carlton, Trial Dep. at 74) ("If I used the higher estimate [of lives saved], the 10,441," the higher estimate of the value of a live saved is "roughly $10 million, then you get over $100 billion."); [redacted]

Response to Finding No. 1124.1

The proposed finding is confusing, vague, and mislead, and this Court should reject Respondents' proposed evidence. The proposed finding is confusing because the phrase "the lower end of lives saved and the value of lives saved" is unclear, at best. The proposed finding is also vague. Respondents fail to define and/or quantify the terms "the estimate," "lower end," "higher estimate," and "over $100 billion." Lastly, the proposed finding is misleading, in that it assumes the Transaction will "accelerate the adoption of Galleri" by one year, thereby resulting in "lives saved." [redacted]

[redacted]

[redacted]

1124.2 In addition, the estimate does not include the value of international acceleration, which would double the benefits. (RX6000 (Carlton Trial Dep. at 200); RX3864 (Carlton Expert Report) ¶ 119 n.291 ("My calculations include U.S. lives only. Acceleration will also save lives in other countries. With a one-year acceleration, an additional 10.4 million tests would be performed outside of the U.S. over the nine-year period 2022–2030. If the lives saved by these tests are valued the same as lives saved in the U.S., then the total benefits from acceleration would be more than double what I calculate.").)

Response to Finding No. 1124.2

The proposed finding is vague and should be rejected by this Court. Respondents fail to define the term "the estimate," "the value," "international acceleration," "acceleration," and "the benefits." The proposed finding is misleading, in that it assumes the Transaction will result in some undisclosed amount of "international acceleration," thereby resulting in "lives saved."

[redacted]

[redacted] This statement is supported only by Dr. Carlton's self-serving testimony.

[redacted]

[redacted]

1124.3 Dr. Carlton's estimate also does not include the fact that acceleration of GRAIL's sales will allow GRAIL to improve the quality of the Galleri test by generating data quicker. (RX6000 (Carlton Trial Dep. at 78); RX3864 (Carlton Expert Report) at 82.)

Response to Finding No. 1124.3

The proposed finding is misleading and vague, and it should be rejected by this Court. The proposed finding is misleading. Whether "the acceleration of GRAIL's sales will allow GRAIL to improve the quality of the Galleri test" is not a "fact," even though Respondents characterize it as such. Similarly, the proposed finding is vague, in that Respondents fail to define the terms "Dr. Carlton's estimate," "acceleration," "GRAIL's sales," "improve the quality," and "quicker."

Lastly, the proposed finding is misleading, insofar as Dr. Carlton's "estimate" assumes the Transaction will "accelerate the adoption of Galleri" by one year, thereby resulting in "lives saved."

[redacted]

[redacted]

1125. The size of the lives saved efficiency is also validated by alternative calculation methods. (RX 6000 (Carlton, Trial Dep. at 76–78).)

Response to Finding No. 1125

The proposed finding is misleading, against the weight of the evidence, vague, and should be rejected by this Court. The proposed finding is misleading for two reasons. [redacted]

[redacted] Second, this proposed finding is misleading, insofar as it implies that the Transaction will result in the acceleration of Galleri's "adoption." [redacted]

[redacted]

[redacted]

1125.1 Dr. Carlton calculated the value of life-years saved by valuing a life year at between $100,000 and $150,000. Using this calculation, the lives saved from a one year acceleration in the U.S. were still valued at least between $11.5 and $17 billion. (RX 6000 (Carlton, Trial Dep. at 76–78); [redacted]

Response to Finding No. 1125.1

The proposed finding is vague, confusing, improper, and should be disregarded by this Court. [redacted]

The proposed finding is misleading, insofar as Dr. Carlton's "calculation" assumes the Transaction will "accelerate the adoption of Galleri" by one year, thereby resulting in "lives saved." [redacted]

[redacted]

1126. The lives saved efficiency was not refuted by Complaint Counsel.

Response to Finding No. 1126

The proposed finding is uncited, improper, misleading, and should be rejected by this

Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

[redacted] This proposed finding is misleading, insofar as it implies that the Transaction will result in the acceleration of Galleri's "adoption." [redacted]

As the "lives saved" efficiency would be a by-product of Respondents' claimed acceleration efficiency, this proposed finding is misleading. It is not true that this efficiency "was not refuted by Complaint Counsel." [redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

1126.1 [redacted]

Response to Finding No. 1126.1

The proposed finding is inaccurate, misleading, mischaracterizes Dr. Navathe's testimony, and should be rejected by this Court. The proposed finding is inaccurate and misleading. There is no "factual evidence" that there will be acceleration of the Galleri test. The only basis for this claim is the self-serving testimony of Respondents' executives.

Respondents also mischaracterize Dr. Navathe's testimony. [redacted] These are not "quibbles," as

Respondents put it. These are Dr. Navathe's evaluations of fundamental flaws in Dr. Carlton's analysis.

[redacted]

1126.2 [redacted] is directly contradicted by the Department of Health and Human Services and FDA guidance which states that "[t]he approach for valuing mortality risk reductions is generally based on estimates of the value per statistical life". (RX3967 (U.S. Dept. Health and Human Services) at 13; PX7139 (Navathe Trial Dep. at 142–45); *see also* RX3968 (Mammography Quality Standards Act; Amendments to Part 900 Regulations) (quantifying the benefits derived from reduced mortality from a revised rule regarding breast cancer screening using the value of a statistical life); PX7139 (Navathe Trial Dep. at 146–48).)

Response to Finding No. 1126.2

[redacted]

[redacted]

1126.3 [redacted]

[redacted] PX0221 (Hubbell et. al 2021 Supplementary Methods and Materials) at 4 ("As the holdout demonstrated the average performance was compatible with the cross-validated training set, we use here the training set sensitivities which allow resolution of individual cancer type sensitivities by stage"); RX6000 (Carlton Trial Dep. at 77) ("My understanding from the article, as well as discussions with Dr. Hubbell, is that there is no bias.").)

Response to Finding No. 1126.3

[redacted]

[redacted]

[redacted]

1126.4 Dr. Navathe's claim that Dr. Carlton should not have assumed perfect compliance with the Galleri testing regime overlooks the fact that doing so makes Dr. Carlton's estimate more conservative, not less. (RX6000 (Carlton Trial Dep. at 78).)

Response to Finding No. 1126.4

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Carlton's trial deposition to support this proposed finding, in contravention of this Court's Order. (*see* Order on Post-Trial Findings at 3). Importantly, the proposed finding does not concern Dr. Carlton's report, but rather a proposed fact regarding Dr. Navathe's claim. Respondents improperly rely on Dr. Carlton's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or elsewhere, and therefore this Court should disregard Respondents' proposed finding.

What is more, the proposed finding is clearly outside the scope of Dr. Carlton's report and is therefore improper expert testimony. This Court ordered that "[a]n expert witness' testimony is limited to opinions contained in the expert report[.]" (Scheduling Order at 9). Here, Dr. Carlton's testimony concerned a rebuttal expert report, which was completed after Respondents served Dr. Carlton's expert report. This testimony is therefore outside the scope of Dr. Carlton's expert report, in contravention of this Court's Scheduling Order.

[redacted]

[redacted]

[redacted]

1126.5 Moreover, and most notably, none of Dr. Navathe's criticisms change the fundamentals of Dr. Carlton's conclusion: thousands of lives will be saved by the Transaction and the value of those lives is in the billions of dollars. (*See* RX 6000 (Carlton, Trial Dep. at 73–75).) None of Complaint Counsel's experts reliably refute this assertion.

Response to Finding No. 1126.5

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite only to Dr. Carlton's trial deposition to support this proposed finding, in contravention of this Court's Order. (*see* Order on Post-Trial Findings at 3). Importantly, Respondents propose a fact regarding whether Dr. Navathe's rebuttal "change[s] the fundamentals of Dr. Carlton's conclusion"—this is not an expert opinion,

but a separate factual proposition. Respondents improperly rely on Dr. Carlton's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or elsewhere, and therefore this Court should disregard Respondents' proposed finding.

What is more, the proposed finding is clearly outside the scope of Dr. Carlton's report, and is therefore improper expert testimony. This Court ordered that "[a]n expert witness' testimony is limited to opinions contained in the expert report[.]" (Scheduling Order at 9). Here, Dr. Carlton's testimony concerned a rebuttal expert report, which was completed after Respondents served Dr. Carlton's expert report. This testimony is therefore outside the scope of Dr. Carlton's expert report, in contravention of this Court's Scheduling Order. Respondents attempt to offer impermissible surrebuttal testimony, and this Court therefore should disregard Respondents' proposed finding.

The proposed finding is misleading and against the weight of the evidence. The proposed finding is misleading insofar as it (or rather, Dr. Carlton) assumes "thousands of lives will be saved by the Transaction[.]" [redacted]

The second sentence of proposed finding is uncited, improper, and should be rejected by this Court. It is unsupported because no evidence is cited for the factual proposition. This Court

has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of the second sentence of their proposed finding, in direct contravention of this Court's Order.

The second sentence of this proposed finding is not a finding of fact, but a legal conclusion. Whether Complaint Counsel's "experts reliably refute [Dr. Carlton's] assertion" is an evidentiary question for this Court to decide, and Respondents improperly present it as a fact here. Moreover, Respondents' proposed finding is vague, as they fail to define the term "reliably refute."

[redacted]

[redacted]

[redacted]

1126.6 Complaint Counsel's economist, Dr. Fiona Scott Morton, speculates that, but for the Transaction, other MCED tests currently in development could be better and therefore might result in more lives saved. [redacted] 232–33).)

Response to Finding No. 1126.6

The proposed finding is misleading, misstates Dr. Scott Morton's testimony, is vague, and should be disregarded by this Court. The proposed finding is misleading and misstates Dr. Scott Morton's testimony. [redacted] Dr. Scott Morton does not focus on one particular MCED which "could be better and . . . result in more lives saved," as Respondents suggest. Instead, she expressed her opinion that, absent the transaction, there would be "competition among MCED developers" which would "be better," as Respondents put it, and "result in more lives saved."

The proposed finding is vague. Respondents fail to define the terms "speculates," "other MCED tests," "could be better," "might result," and "more lives."

[redacted]

1126.7 However, not only is this argument not supported by the factual evidence but also it asks this Court to accept speculation regarding potential MCED tests over

factual evidence regarding existing efficiencies. It is undisputed that Galleri is the only MCED test on the market. (*See*, *e.g.*, Complaint Counsel Opening Statement, Tr. 11 ("[W]e agree that MCED tests is a developing market, meaning, GRAIL is the only company that is offering MCED tests for sale in even a limited capacity.").) Also, there is unrefuted evidence that Illumina will accelerate Galleri and thereby save more lives. (deSouza (Illumina) Tr. 2411; Aravanis (Illumina) Tr. 1942; Febbo (Illumina) Tr. 4327; Flatley (Illumina) Tr. 4089; [redacted] Ofman (GRAIL) Tr. 3283, 3309; Freidin (GRAIL) Tr. 2999; [redacted] *see also* Complaint Counsel Opening Statement, Tr. 11; Conroy (Exact/Thrive) Tr. 1739; Chahine (Helio) Tr. 1132–33; Nolan (Freenome) Tr. 2725; [redacted] Fiedler (FMI) Tr. 4474.) In contrast, there is no guarantee that any other MCED test will ever be released much less that they will be able to save the same number of lives as GRAIL or save those lives sooner. Dr. Scott Morton's claims about the effects of other tests are thus baseless speculation.

Response to Finding No. 1126.7

[redacted]

[redacted]

B. The Reunion of Illumina and GRAIL will Accelerate Market Access to a Life Saving Test

1127. The reunion of Illumina and GRAIL will accelerate market access to Galleri.

Response to Finding No. 1127

The proposed finding is uncited, improper, misleading, against the weight of the evidence, vague, and should be rejected by this Court. First, the proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

[redacted]

The acceleration claims also appear inconsistent with Illumina's valuation of its Contingent Value Rights ("CVRs"), which Illumina issued when it consummated its acquisition of Grail. CVRs are similar to a royalty and entitle holders to a [redacted]; (PX0074 (Illumina) at 217 (Illumina Amended S-4)); (Bishop (Grail) Tr. 1356). In Illumina's Q3 2021 Quarterly Report, which its CEO reviewed and certified pursuant to Sarbanes-Oxley, Illumina valued the CVR consideration as of the Acquisition's August 18, 2021, close date at only $1.621 million. (PX0408 (Illumina) at -018 (Illumina Form 10-Q, October 3, 2021)) (measuring the $762 million CVR valuation as of the acquisition's August 18, 2021 close date); (PX0377 (Illumina) at -002 (Illumina Press Release, August 26, 2021) (announcing that "[h]olders of approximately 47% of GRAIL equity interests … elected to receive the CVR consideration," and thus, had 100% of Grail's equity holders elected to receive the CVR consideration, Illumina's 10-Q would have valued the total

CVR consideration at approximately $1,621 million (of which 47% is $762 million)). This implied 10-Q valuation of $1,621 million [redacted]

Lastly, the proposed finding is vague. Respondents fail to define and/or quantify the terms "accelerate" and "market access." Therefore, this Court should disregard the proposed finding.

> 1127.1 To achieve widespread adoption, GRAIL will need to achieve regulatory approval and payor coverage for Galleri. (Bishop (GRAIL) Tr. 1343–45; Conroy (Exact/Thrive) Tr. 1734–35; Gao (Singlera) Tr. 2889–91; [redacted]; Rabinowitz (Natera) Tr. 298–99.)

Response to Finding No. 1127.1

The proposed finding is impermissibly vague and should be rejected by this Court. Respondents fail to define and/or quantify the terms "achieve," "widespread," "adoption," "regulatory approval," and "payer coverage." Therefore, this Court should disregard the proposed finding.

> 1127.2 While Galleri was launched in June 2021, it has a long way to go in order to obtain widespread market adoption. (Bishop (GRAIL) Tr. 1322–23, 1344–45; [redacted] Aravanis (Illumina) Tr. 1892, 1943, 1947.)

Response to Finding No. 1127.2

The proposed finding is impermissibly vague and should be rejected by this Court. Respondents fail to define the terms "was launched," "a long way to go," and "widespread market adoption." And, rather than referencing pre-acquisition, ordinary course documents to demonstrate Galleri "has a long way to go," Respondents cite only to the unfounded, self-serving testimony of Grail and Illumina executives, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of

foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1127.3 GRAIL is a new company with no expertise or experience in achieving regulatory approval and payor coverage for an NGS test. [redacted] Freidin (GRAIL) Tr. 2980; Aravanis (Illumina) Tr. 1943, 1947; PX6001 (Deverka Trial Dep. at 67).)

Response to Finding No. 1127.3

[redacted]

[redacted]

[redacted]

1127.4 Illumina, in contrast, has unique experience and capabilities that will enable the acceleration of market access for Galleri. (deSouza (Illumina) Tr. 2348, 2351–52; Aravanis (Illumina) Tr. 1943–44, 1947; Qadan (Illumina) Tr. 4158–59; [redacted] Freidin (GRAIL) Tr. 2980; PX6001 (Deverka Trial Dep. at 63).)

Response to Finding No. 1127.4

The proposed finding is misleading, against the weight of the evidence, unreliable, and should be rejected by this Court. The proposed finding is misleading, insofar as it implies

[redacted]

[redacted]

And, rather than referencing pre-acquisition, ordinary course documents to demonstrate Galleri "has a long way to go," Respondents cite only to the unfounded, self-serving testimony of Grail and Illumina executives, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite to Dr. Deverka's trial deposition to support this proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Lastly, the proposed finding is vague. Respondents fail to define the terms "in contrast," "unique experience," and "unique . . . capabilities," "the acceleration," and "market access." Therefore, this Court should disregard the proposed finding.

1127.5 Hence, the reunion of Illumina and GRAIL will substantially accelerate market access for Galleri. (deSouza (Illumina) Tr. 2343–44; Aravanis (Illumina) Tr. 1945, 1948; Febbo (Illumina) Tr. 4345–46, 4360; Qadan (Illumina) Tr. 4158–59; Flatley (Illumina) Tr. 4082; Bishop (GRAIL) Tr. 1417; [redacted] Freidin (GRAIL) Tr. 2980; [redacted] RX6001 (Deverka Trial Dep. at 81); RX3867 (Deverka Expert Report) ¶¶ 112 n.217; 121 RX3867 (Deverka Expert Report) ¶ 112 n.217; RX6001 (Deverka Trial Dep. at 64–86).)

Response to Finding No. 1127.5

The proposed finding is vague, misleading, unreliable, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "substantially," "accelerate," and "market access."

The proposed finding is misleading, insofar as it implies the Transaction "will substantially accelerate market access for Galleri." [redacted]

Rather than referencing pre-acquisition, ordinary course documents for such a sweeping "factual proposition," Respondents cite only to the unfounded, self-serving testimony of Grail and Illumina executives, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite to Dr. Deverka's expert report and

trial deposition to support this proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Indeed, Respondents cite to Dr. Deverka four times in support of this factual proposition.

The acceleration claims also appear inconsistent with Illumina's valuation of its Contingent Value Rights ("CVRs"), which Illumina issued when it consummated its acquisition of Grail. CVRs are similar to a royalty and entitle holders to a [redacted]; (PX0074 (Illumina) at 217 (Illumina Amended S-4)); (Bishop (Grail) Tr. 1356). In Illumina's Q3 2021 Quarterly Report, which its CEO reviewed and certified pursuant to Sarbanes-Oxley, Illumina valued the CVR consideration as of the Acquisition's August 18, 2021, close date at only $1.621 million. (PX0408 (Illumina) at -018 (Illumina Form 10-Q, October 3, 2021)) (measuring the $762 million CVR valuation as of the acquisition's August 18, 2021 close date); (PX0377 (Illumina) at -002 (Illumina Press Release, August 26, 2021) (announcing that "[h]olders of approximately 47% of GRAIL equity interests … elected to receive the CVR consideration," and thus, had 100% of Grail's equity holders elected to receive the CVR consideration, Illumina's 10-Q would have valued the total CVR consideration at approximately $1,621 million (of which 47% is $762 million)). This implied 10-Q valuation of $1,621 million [redacted]

Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

1128. GRAIL currently has limited availability.

Response to Finding No. 1128

The proposed finding is uncited, improper, vague, and should be rejected by this Court. First, the proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

Second, the proposed finding is confusing and vague. The proposed finding is confusing and vague because Respondents do not define or explain what is meant by "limited availability." Therefore, this Court should disregard the proposed finding.

1128.1 GRAIL launched Galleri as an LDT in June 2021. (Bishop (GRAIL) Tr. 1322, 1344–45; [redacted] Aravanis (Illumina) Tr. 1892 ("The Galleri test was launched as an LDT").)

Response to Finding No. 1128.1

Complaint Counsel has no specific response to this proposed finding.

1128.2 Galleri is currently available for $949, a price that many individuals cannot afford. (Bishop (GRAIL) Tr. 1322 ("Q. What is the current list price for Galleri? A. $949."); deSouza (Illumina) Tr. 2342 ("Today, the Galleri test is available for $950, and it's a self-pay test primarily. There is a part of the American population that can afford that as a regular test, but there is a lot of this country that cannot afford a thousand-dollar test, and so we feel a sense of urgency to drive reimbursement as quickly as possible.").)

Response to Finding No. 1128.2

The proposed finding is vague, unsupported, unreliable, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the term "many individuals." For similar reasons, the proposed finding is unsupported. Neither of the cited

sources supports the contention that "many individuals cannot afford" Galleri. At best, Mr. deSouza testified that "there is a lot of this country that cannot afford" Galleri as it is currently priced. (deSouza, Tr. 2342). But it is unclear from Respondents' finding if "a lot of this country" is equal to "many individuals." Lastly, even assuming the two are equal, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive and a Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1128.3 Galleri is not approved by the FDA or covered by CMS or private payors. (Bishop (GRAIL) Tr. 1323 ("Q. GRAIL's Galleri test is not currently covered by Medicare; is that right? A. That's right. Q. And Galleri is not widely reimbursed by private insurers yet either; right? A. To my knowledge, it's not reimbursed by any private insurers as of today."); [redacted] Aravanis (Illumina) Tr. 1943, 1947.)

Response to Finding No. 1128.3

Complaint Counsel has no specific response to this proposed finding.

> 1128.4 At the time of live hearing, Galleri has only had limited sales of approximately three to four thousand tests. [redacted] Freidin (GRAIL) Tr. 2969 ("I think we're around the 3,000–ish range.").)

Response to Finding No. 1128.4

The proposed finding is vague and unreliable, and this Court should therefore disregard Respondents' proposed evidence. The proposed finding is also vague. Respondents fail to define the term "limited sales." And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of two Grail executives, which is uncorroborated by any ordinary course documents or analysis. Given the

inherent unreliability of this testimony as well as lack of foundation or explanation for the executives' base conjecture, this proposed finding of fact should be disregarded.

1129. Widespread market access to Galleri will depend on FDA, CMS and payor approval.

Response to Finding No. 1129

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is also vague. Respondents fail to define the terms "[w]idespread" and "market access." Therefore, this Court should disregard the proposed finding.

1129.1 Numerous fact witnesses, including third-party witnesses called by Complaint Counsel, testified that widespread adoption of an MCED test like Galleri will require FDA, CMS and payor approval. (Bishop (GRAIL) Tr. 1343–45; Conroy (Exact/Thrive) Tr. 1734–35; Gao (Singlera) Tr. 2889–91; [redacted] Rabinowitz (Natera) Tr. 298–99.)

Response to Finding No. 1129.1

The proposed finding is vague, misleading, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the terms "[n]umerous," and "widespread adoption." Similarly, the proposed finding is misleading. Many of the witnesses cited by Respondents in support of this finding do not address what is necessary for "widespread adoption." For example, in the cited portion of the transcript, Dr. Gao does not talk about achieving "widespread adoption" at all. (Gao (Singlera), Tr. 2889-91). And [redacted] and Dr. Rabinowitz similarly do not discuss what is necessary to achieve "widespread adoption," but

do discuss the importance of FDA approval in bringing an MCED test to market. [redacted] [redacted] Rabinowitz (Natera), Tr. 298-99). Therefore, this Court should disregard the proposed finding.

1129.2 [redacted]

Response to Finding No. 1129.2

The proposed finding is vague and should be rejected by this Court. Respondents fail to define the terms [redacted] Therefore, this Court should disregard the proposed finding.

1129.3 As Dr. Deverka further explained: A novel test like Galleri "needs to have a premarket authorization, so clearance by the FDA. And how that's relevant for payers is that for the Medicare pathway it's actually a requirement to have an FDA-approved or cleared test. And while private payers can choose to pay for a laboratory-developed test, they sometimes pay addition- – give additional weight to the fact that a test has received FDA approval because it's essentially an imprimatur of quality and that the FDA with its rigorous process has approved the test." (RX 6001 (Deverka Trial Dep. at 39).)

Response to Finding No. 1129.3

Complaint Counsel has no specific response to this proposed finding.

1129.4 [redacted]

Response to Finding No. 1129.4

Complaint Counsel has no specific response to this proposed finding.

1129.5 [redacted]

Response to Finding No. 1129.5

Complaint Counsel has no specific response to this proposed finding, except that [redacted]

1130. GRAIL is inexperienced in obtaining FDA approval, CMS coverage and private payor approval.

Response to Finding No. 1130

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is also vague. Respondents fail to define the term "inexperienced," which is a relative term and, without definition, communicates no factual information whatsoever.

The proposed finding is also misleading and against the weight of the evidence, which demonstrates that Grail is already pursuing FDA approval aggressively, [redacted] Therefore, this Court should disregard the proposed

finding.

1130.1 [redacted]

Response to Finding No. 1130.1

[redacted]

[redacted]

[redacted]

[redacted]

1130.2 Aaron Freidin, Vice President of Finances at GRAIL, testified that Illumina has more experience "[c]ompared to what GRAIL's internal capabilities are and what our history is with the FDA today." (Freidin (GRAIL) Tr. 2980.)

Response to Finding No. 1130.2

The proposed finding is misleading and unreliable, and this Court therefore should disregard Respondents' proposed evidence. The proposed finding is misleading and against the weight of the evidence, which demonstrates that Grail is already pursuing FDA approval aggressively, [redacted]

Rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed

finding of fact should be disregarded. The proposed finding is also unreliable, as Mr. Freidin is a Vice President for Grail, and his foundation to opine on Illumina's "experience" as compared to Grail is unclear. [redacted]

Given this evidence, it is unclear what basis Mr. Freidin has to compare Illumina's "experience" to Grail's. Therefore, this Court should disregard the proposed finding.

> 1130.3 Dr. Aravanis, former head of R&D at GRAIL, testified that GRAIL has no experience getting FDA approval and payor coverage. (Aravanis (Illumina) Tr. 1943, 1947.)

Response to Finding No. 1130.3

The proposed finding is misleading, against the weight of the evidence, unreliable, and should be disregarded by this Court. The proposed finding is misleading and against the weight of the evidence, which demonstrates that Grail is already pursuing FDA approval aggressively, [redacted]

Rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony

as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted]

He has no foundation to speak to Grail's currently experience regarding FDA approval and payer coverage, nor does he have foundation regarding the experiences of Grail's employees regarding FDA approval and payer coverage. Therefore, this Court should disregard the proposed finding.

1130.4 [redacted]

Response to Finding No. 1130.4

The proposed finding is vague, misleading, against the weight of the evidence, and should be disregarded by this Court. Respondents fail to define the terms "their," "they," "extensive," "track record," "successfully," and "to payer coverage" in the first sentence of the proposed finding. In the proposed finding's second sentence, Respondents fail to define the terms "relatively young" and "significantly newer." For similar reasons, the second sentence is confusing because, since no Grail product has received payer coverage, no one—including anyone at Illumina—would have "prior experience receiving coverage for a GRAIL product."

The proposed finding is misleading and against the weight of the evidence, which demonstrates that Grail is already pursuing FDA approval aggressively, [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1130.5 Complaint Counsel did not put forward any fact witness that disagreed with this assessment.

Response to Finding No. 1130.5

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the term "this assessment." Therefore, this Court should disregard the proposed finding.

1130.6 [redacted]

Response to Finding No. 1130.6

The proposed finding is vague, misleading, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the term "such experience." [redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

1131. Illumina is highly experienced in obtaining FDA approval, CMS coverage and private payor approval for NGS products.

Response to Finding No. 1131

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the terms "highly experience" and "NGS products."

The proposed finding is misleading and against the weight of the evidence, [redacted]. Therefore, this Court should disregard the

proposed finding.

> 1131.1 Illumina draws on a number of functions to support its regulatory and market access efforts. (Febbo (Illumina) Tr. 4317; (RX6001 (Deverka Trial Dep. at 65).)

Response to Finding No. 1131.1

The proposed finding is vague, improper, unsupported, unreliable, and should be rejected by this Court. The proposed finding is impermissibly vague. Respondents fail to define and/or quantify the terms "a number of" and "functions."

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents cite to Dr. Deverka's trial deposition to support this proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and therefore this Court should disregard Respondents' proposed finding.

Outside of Dr. Deverka's improper testimony, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

> 1131.2 Illumina has built up teams with a large number of experienced individuals able to focus on regulatory and market access activities. (Febbo (Illumina) Tr. 4319, Qadan, Tr. 4113; (RX6001 (Deverka Trial Dep. at 65).)

Response to Finding No. 1131.2

The proposed finding is vague, misleading, unreliable, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "built up," "a large

number," "experienced individuals," and "regulatory and market access activities."

The proposed finding is misleading, [redacted]

Rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of two Illumina executives, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executives' base conjecture, this proposed finding of fact should be disregarded.

> 1131.3 In the past 3–4 years, Illumina's medical team has grown from 25 to 160 individuals. This required selecting employees with relevant expertise and training them in the relevant technologies, which can take 6 to 12 months per employee. (Febbo (Illumina) Tr. 4319.)

Response to Finding No. 1131.3

The proposed finding is unreliable and should be disregarded by this Court. Rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1131.4 In the past 3–4 years, Illumina has also built up a market access group consisting of three functions: (1) strategy and operations, (2) health economics and (3) outcomes and payer partners. (Qadan Tr. 4113–14.) Illumina created this group to facilitate coverage and reimbursement for genomics in clinical practice. (Qadan (Illumina) Tr. 4113.) The team contains employees with many different areas of expertise, including health economists, individuals with experience working with payors and individuals with experience in genomics. (Qadan (Illumina) Tr. 4115.) Illumina is continuing to expand its budget and headcount in the market access group. (Qadan (Illumina) Tr. 4118–19.)

Response to Finding No. 1131.4

The proposed finding is vague, unreliable, misleading, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "built up," "outcomes," "many different areas," and "continuing to expand."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading, [redacted] Therefore, this Court should disregard the proposed finding.

1131.5 Illumina's regulatory and market access teams have extensive and deep experience working with regulators and payors in the U.S. and internationally. (Febbo (Illumina) Tr. 4338–43.)

Response to Finding No. 1131.5

The proposed finding is vague, unreliable, confusing, misleading, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the terms "extensive . . . experience" and "deep experience."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is also confusing. [redacted]

The proposed finding is misleading, [redacted]

[redacted]

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

> 1131.6 Illumina's regulatory team has extensive expertise obtaining FDA clearances and approvals for diagnostic tests. Illumina has successfully obtained 510(k) clearance for a cystic fibrosis test and a PMA in cancer treatment selection for an extended RAS panel called Praxis. (Febbo (Illumina) Tr. 4338–43; 4113.) Illumina has been working on the approval of a PMA in NIPT and therapy selection. (Febbo Tr. 4381–92.) Illumina also has experience bringing its next-generation sequencing products through FDA clearance. (Febbo (Illumina) Tr. 4338–39.)

Response to Finding No. 1131.6

The proposed finding is vague, unreliable, confusing, misleading, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "extensive expertise," "diagnostic tests," and "been working on."

Rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is confusing. Respondents do not indicate the relevance of obtaining 510(k) clearance from the FDA. This is not the kind of FDA clearance Grail would need for FDA approval of the Galleri test.

The proposed finding is misleading for two reasons. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Second, the proposed finding is misleading because it implies [redacted] Therefore, this Court should disregard the proposed finding.

> 1131.7 Illumina frequently interacts with the FDA, including through an educational program to teach the FDA about next-generation sequencing. (Febbo Tr. 4341.) Dr. Febbo testified that "both through my personal interactions and discussions with the FDA and FDA leaders, I have compliments that we have helped them understand next-generation sequencing, and I've seen -- you know, I have seen evolution and improvements in their approach to next-generation sequencing." (Febbo Tr. 4342–43.)

Response to Finding No. 1131.7

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "frequently," "interacts," "I have compliments," and "evolution and improvements in their approach."

Rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is

uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading insofar as it [redacted] Therefore, this Court should disregard the proposed finding.

> 1131.8 Illumina has also developed a quality management system compliant with the requirements of the FDA. (Febbo Tr. 4347.) This system took over seven years to develop and can be used on new projects. (*Id.*)

Response to Finding No. 1131.8

The proposed finding is vague. Respondents fail to define the terms "quality management system," "over seven years," and "can be used on new projects." Importantly, Respondents fail to indicate whether their term "new projects" includes an MCED test. Rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1131.9 Illumina's market access team has extensive experience working with CMS and private payors. (Qadan (Illumina) Tr. 4154.) Illumina has extensive experience working on clinical studies and developing real world data necessary to show clinical utility. (Qadan (Illumina) Tr. 4156.) Through its partnerships and models Illumina can help show economic value of Galleri. (Qadan (Illumina) Tr. 4156–57.)

Response to Finding No. 1131.9

The proposed finding is vague. Respondents fail to define the terms "extensive experience." And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading, insofar as it implies [redacted]

1131.10 Illumina has also built up a reputation in market access over three to four years. (Qadan (Illumina) Tr. 4118.) Illumina's broad experience with genomics and its longstanding relationships with payors such as Genomics England allow it to easily develop partnerships with payors. (Qadan (Illumina) Tr. 4416–17.) In addition, Illumina's growing reputation in the field has enabled it to attract the best talent. (Qadan (Illumina) Tr. 4117.)

Response to Finding No. 1131.10

The proposed finding is vague, unreliable, misleading, against the weight of the evidence,

and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "built up a reputation," "broad experience," "longstanding relationships," "easily develop," "growing reputation," "in the field," and "the best talent."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading, insofar as it implies [redacted] Therefore, this Court should disregard the proposed finding.

1131.11 The market access group is currently working on NIPT, tumor comprehensive and whole genome sequencing. (Qadan (Illumina) Tr. 4121.)

Response to Finding No. 1131.11

The proposed finding is vague, unreliable, and should be disregarded by this Court. The

proposed finding is vague. Respondents fail to define the terms "[t]he market access group" and "is currently working on." And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1131.12 In NIPT, Illumina spearheaded a risk-sharing agreement with Harvard Pilgrim Health Care to develop the evidence needed to expand coverage of NIPT tests for all pregnancies. (Qadan (Illumina) Tr. 4123–24.) The publication of the work with Harvard Pilgrim has increased Illumina's reputation and resulted in a significant increase in coverage for NIPT. (Qadan (Illumina) Tr. 4125–26.) Illumina also has a partnership with Providence HealthCare. (Qadan (Illumina) Tr. 4126.)

Response to Finding No. 1131.12

The proposed finding is vague, confusing, unreliable, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "spearheaded," "expand coverage," "increased Illumina's reputation," and "significant increase." The proposed finding is also confusing, as Respondents do not explain what it means for a "reputation" to "increase," nor do they indicate how Mr. Qadan determined that its work with Harvard Pilgrim "increased Illumina's reputation." And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1131.13 In tumor genomic comprehensive genomic profiling, Illumina has developed partnerships with Providence in the U.S., the Belgian Society of Oncology, University of Melbourne and partnerships in Japan. (Qadan (Illumina) Tr. 4132.) The total number of patients globally covered for tumor comprehensive genomic profiling increased by almost six times. (Qadan (Illumina) Tr. 4133.)

Response to Finding No. 1131.13

The proposed finding is confusing, vague, unreliable, and should be disregarded by this Court. The proposed finding is confusing. It is unclear from the finding whether Respondents contend that "the total number of patients globally covered . . . increased by almost six times," because of Illumina's partnerships, or whether that increase occurred for some other reason. The proposed finding is also vague. Respondents fail to define the term "increased by almost six times." It is unclear what this figure increased from—i.e., without knowing the base figure, no factual information is conveyed by knowing it "increased by almost six times." The figure could still be zero and have "increased by almost six times." No factual information is conveyed at all by the second sentence of this proposed finding.

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1131.14 In whole genome sequencing, Illumina has worked closely with partners to develop evidence of clinical utility through publications. Illumina has also spent significant time developing evidence of economic utility as well as a model of economic utility. (Qadan (Illumina) Tr. 4134.) Illumina also has partnerships with many U.S. hospitals such as Rady Children's Hospital in San Diego, Medicaid in California and Michigan and countries and healthcare systems outside the U.S. such as Genomics England, the State of Queensland in Australia, in Taiwan and in Israel. (Qadan (Illumina) Tr. 4134–35.) Illumina has also entered into risk sharing agreements with Harvard Pilgrim and the State of Queensland in Australia. (Qadan (Illumina) Tr. 4136.) Coverage for whole genome sequencing has increased from nothing to 32–36 million in the U.S and over 1 billion worldwide. (Qadan (Illumina) Tr. 4137–38.)

Response to Finding No. 1131.14

The proposed finding is confusing, vague, unreliable, and should be disregarded by this Court. The proposed finding is confusing. It is unclear from the finding whether Respondents

contend that "[c]overage for whole genome sequencing has increased from nothing to 32-36 million in the U.S. and over 1 billion worldwide," because of Illumina's partnerships. The proposed finding is also vague. Respondents fail to define the term "worked closely with," significant time," "a model of economic utility," "many U.S. hospitals," "many . . . healthcare systems outside the U.S." It is unclear what this figure increased from—i.e., without knowing the base figure, no factual information is conveyed by knowing it "increased by almost six times." The figure could still be zero and have "increased by almost six times." No factual information is conveyed at all by the second sentence of this proposed finding.

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1131.15 Illumina has also developed a budget model for NIPT and whole genome sequencing which can be used as a part of entering into partnerships with payors in the future and with payors outside the U.S. This took one to two years to develop. (Qadan (Illumina) Tr. 4128.) This budget model can be used to aid for future models in cancer screening. (Qadan (Illumina) Tr. 4129–30.)

Response to Finding No. 1131.15

The proposed finding is vague, unreliable, unsupported, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the terms "a budget model." And, rather than referencing pre-acquisition, ordinary course documents (i.e., a version of the budget model being discussed), Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be

disregarded. The proposed finding also provides no evidence, other than Mr. Qadan's testimony, to support the contention that "[t]his budget model can be used to aid for future models in cancer screening." There is no evidence to indicate that this "budget model" can be applied to cancer screening, how it would be applied to cancer screening, what would be required to apply it to cancer screening, or how expensive it would be to apply it to cancer screening. Here, as they have throughout this litigation, Respondents provide zero substance to support the base conjecture of their business executives. Therefore, this Court should disregard the proposed finding.

1131.16 [redacted]

Response to Finding No. 1131.16

The proposed finding is vague, unreliable, misleading, and should be disregarded by this Court. The proposed finding is vague. [redacted]

self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading insofar as it implies [redacted]

Therefore, this Court should disregard the proposed finding.

> 1131.17 Illumina also has unique expertise in NGS technology. This expertise is critical when it comes to engaging in market access and regulatory efforts for a new technology, such as cancer screening. As Dr. Febbo testified "our technology is still relatively new to all of the stakeholders, to payers, to regulators, to governments, and while there's early recognition of the promise and, you know, people are starting to see the benefits of genomics, there's really a lack of understanding and certainly a lack of deep knowledge. So it's really important that as we bring the story forward, we have expertise on the technology. We are the experts that can educate, that can engage, and help them understand. And the reason that is is that we're asking them and the payers to write a coverage policy on a technology, and for them to be comfortable with the policy, they have to be comfortable that the technology is analytically, clinically valid and has clinical utility. The regulators have to be convinced that they understand the technology enough to know it's safe and effective and can be the back -- the foundation for safe and effective tests. And so by having that expertise in genomics, you're in a much better

> position to help the regulators understand and help regulators evolve their approach to approval or payers evolve their approach to positive policy decisions covering those tests." (Febbo (Illumina) Tr. 4318–19.)

Response to Finding No. 1131.17

The proposed finding is vague, unreliable, unsupported, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the terms "unique expertise," "critical," "a new technology," "relatively new," "early recognition," "really important," "them." And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is unsupported, insofar as Dr. Febbo's quoted and cited testimony does not support the contention that Illumina's claimed "expertise is critical when it comes to engaging in market access and regulatory efforts for a new technology, such as cancer screening." Similarly, there is no support in the finding that "Illumina . . . has unique expertise in NGS technology." Therefore, this Court should disregard the proposed finding.

1132. Numerous witnesses testified to Illumina's experience and expertise in these areas.

Response to Finding No. 1132

The proposed finding is uncited, improper, vague, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct

contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the terms "[n]umerous witnesses," "Illumina's experience and expertise," and "these areas."

Notwithstanding its impropriety, the proposed finding is also misleading and against the weight of the evidence, [redacted] Therefore, this Court should disregard the proposed finding.

> 1132.1 Illumina's Chief Executive Officer, Francis deSouza testified that "we have now, you know, closing in on about ten years' experience working with the FDA. We have since got[ten] other sequencers approved. . . . And on the test side, we're working on getting approval for our TSO 500, we're working on getting approval for our NIPT assay here in the U.S., and we're looking at getting approval for a genetic disease diagnosis workflow as well." (deSouza (Illumina) Tr. 2348.)

Response to Finding No. 1132.1

The proposed finding is vague. Respondents fail to define the terms "about ten years," "other sequencers," "working on," and "looking at." Respondents do not indicate the relevant of Illumina getting "other sequencers approved" to Illumina's ability to get a screening test approved by the FDA. Similarly, Respondents do not indicate the relevance of "working on getting" approvals. Grail, similarly, is "working on getting" approval for it is own test, and so Illumina appears to be in the same position as Grail, with respect to achieving FDA approval for its tests.

To the extent the proposed finding implies [redacted]

[redacted]

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1132.2 With respect to payor coverage, Mr. deSouza testified Illumina "ha[s] been working with payers in the U.S. and around the world, again, for almost a decade. We have a very talented team that has expertise in working with payers and is – and has the right innovation focus to come up with new models to accelerate the evidence generation needed to get payers on board." (deSouza (Illumina) Tr. 2351–52.)

Response to Finding No. 1132.2

The proposed finding is vague, misleading, unreliable, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the terms "working with," "almost a decade," "very talented," "the right innovation focus," "new models," and "accelerate." To the extent that "innovation focus" is necessary to develop the "new models to accelerate the evidence generation needed to get payers on board," Respondents do not indicate how, if at all, that "innovation focus" is unique to Illumina. Similarly, Respondents do not indicate whether the claimed "innovation focus [necessary] . . . to get payers on board," is necessary to get payers on board for Galleri specifically. In other words, Respondents do not

indicate what it is that Illumina can "get payers on board" for.

To the extent the proposed finding implies [redacted]). The evidence indicates that the relevance of any experience Illumina has achieving reimbursement is questionable, at best.

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1132.3 Dr. Aravanis, Chief Technology Officer at Illumina and former head of R&D at GRAIL, testified that "Illumina received the first FDA clearance for a next-generation sequencer. It's received over 70 clearances and registrations around the world in 45 countries. It's received multiple clearances and a PMA approval in the United States." (Aravanis (Illumina) Tr. 1943–44.)

Response to Finding No. 1132.3

The proposed finding is confusing, unclear, misleading, and should be rejected by this Court. The proposed finding is confusing. Respondents fail to make it clear how Illumina receiving "FDA clearance for a next-generation sequencer" has any bearing on Grail's efforts to gain FDA approval for an MCED test. Similarly, it is unclear how receiving "clearances and registrations" internationally has any bearing on Grail's efforts to gain FDA approval for its MCED test.

The proposed finding is misleading, insofar as it implies [redacted] Therefore, this Court should disregard the proposed finding.

> 1132.4 Dr. Aravanis also testified that "Illumina has pioneered multiple approaches to market access, resulting in over 100 million additional patients worldwide covered for whole genome testing for genetic disease over the last two years. In the United States, we have now achieved 200 million people who can receive coverage for comprehensive genomic profiling using NGS technology. These were largely driven by Illumina's market access efforts." (Aravanis (Illumina) Tr. 1947.)

Response to Finding No. 1132.4

The proposed finding is vague, unreliable, misleading, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the terms "multiple approaches," "largely driven," and "market access efforts." Importantly, Respondents claim Illumina "pioneered multiple approach to market access," but does not provide any information here or elsewhere about what those "approaches" are.

And, rather than referencing pre-acquisition, ordinary course documents (e.g., exemplifying the claimed "pioneered . . . approaches"), Respondents cite only to the unfounded, self-serving testimony of a single Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading, insofar as it implies that [redacted]

"[redacted] The evidence indicates that the relevance of any experience Illumina has achieving reimbursement is questionable, at best. Therefore, this Court should disregard the proposed finding.

> 1132.5 Mr. Ammar Qadan, Vice President and Global Head of Market Access at Illumina, provided a detailed overview of Illumina's extensive market access capabilities and the success they have had working with payors in the NGS space. (Qadan (Illumina) Tr. 4158–59.)

Response to Finding No. 1132.5

The proposed finding is vague, misleading, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "a detailed overview," "extensive market access capabilities," "success . . . working with paayors," and "the NGS space."

The proposed finding is misleading, insofar as it implies that [redacted] The evidence indicates that the relevance of any experience Illumina has achieving reimbursement is questionable, at best. Therefore, this Court should disregard the proposed finding.

1132.6 [redacted]

Response to Finding No. 1132.6

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1132.7 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "Illumina has those resources to do those things and have demonstrated doing it in the past." (Freidin (GRAIL) Tr. 2980.)

Response to Finding No. 1132.7

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "those resources," "those things," "doing it," and "in the past." Moreover, Mr. Freidin is a Senior Vice President at Grail. He does not have foundation or basis to discuss whether Illumina has "those resources" or can do "those things." [redacted]

And, rather than referencing pre-acquisition, ordinary course documents (e.g., showing whether Illumina has "those resources"), Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or

explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

To the extent that by "those things" Respondents mean that Illumina has any ability to accelerate Grail's FDA approval or payer coverage, the proposed finding is against the weight of the evidence. [redacted] The evidence indicates that the relevance of any experience Illumina has achieving reimbursement is questionable, at best. Therefore, this Court should disregard the proposed finding.

> 1132.8 Dr. Deverka testified that Illumina has "a track of a market access team having generated the requisite evidence of clinical utility and engagement with payers, both in the U.S. and internationally, to support the use of next-generation sequencing-based tests, so it's really their – their objective track record." (PX6001 (Deverka Trial Dep. at 63).)

Response to Finding No. 1132.8

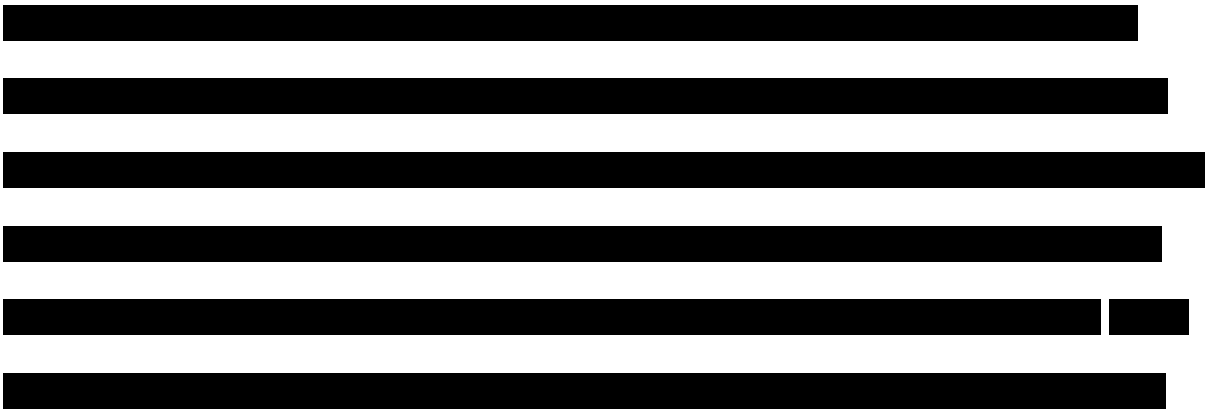
The proposed finding is vague, unclear, unreliable, improper, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "a track of a market access team," "the requisite evidence," "the requisite evidence of . . . engagement with payers," and "objective track record." In particular, it is completely unclear what Respondents and/or Dr. Deverka mean by "the requisite evidence of . . . engagement with payers." It is unclear who determines what the level of

"requisite evidence" is for "engagement with payers, and whether this level is determine by Dr. Deverka out of whole cloth.

And, rather than referencing pre-acquisition, ordinary course documents (e.g., showing whether "Illumina has 'a track of a market access team,'" whatever that may mean), Respondents cite only to the unfounded, self-serving testimony of a their paid expert witness, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the Dr. Deverka's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is improper because this Court held that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." (Order on Post-Trial Findings at 3). Here, Respondents' cite only to Dr. Deverka's trial deposition testimony to support this proposed finding, in contravention of this Court's Order. (*See* Order on Post-Trial Findings at 3). Respondents improperly rely on Dr. Deverka's expert opinions to support this proposed finding, in contravention of this Court's Order, and otherwise have never provided any evidence to support this proposed finding, either here or in Dr. Deverka's report, and therefore this Court should disregard Respondents' proposed finding.

Lastly, the proposed finding is misleading, insofar as Dr. Deverka's testimony implies



[redacted] The evidence indicates that the relevance of any experience Illumina has achieving reimbursement is questionable, at best. Therefore, this Court should disregard the proposed finding.

> 1132.9 Complaint Counsel did not put forward any fact witness that disagreed with this assessment, and its expert witnesses lack the expertise to opine on the issue. [redacted] PX7139 (Navathe Trial Dep. at 97–103); PX7140 (Rothman Trial Dep. at 42–44).)

Response to Finding No. 1132.9

[redacted]

[redacted]

1132.10 The Transaction will accelerate FDA, CMS and payor coverage of Galleri. (deSouza (Illumina) Tr. 2343–44; Aravanis (Illumina) Tr. 1945, 1948; Febbo (Illumina) Tr. 4345–46, 4360; Qadan (Illumina) Tr. 4158–59; Flatley (Illumina) Tr. 4082; Bishop (GRAIL) Tr. 1417; Ofman (GRAIL) Tr. 3346, 3371; Freidin (GRAIL) Tr. 2980; [redacted]

Response to Finding No. 1132.10

[redacted]

[redacted]

1133. Numerous Illumina and GRAIL fact witnesses testified that the reunion of Illumina and GRAIL will accelerate Galleri's path to FDA approval and CMS and private payor coverage.

Response to Finding No. 1133

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This

Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

[redacted]

A cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on

vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90. Therefore, this Court should disregard the proposed finding.

> 1133.1 Francis deSouza, Chief Executive Officer and President of Illumina, testified that: "We also have deep expertise working with payers. We have created innovative programs like risk-sharing agreements with insurance companies where we contribute resources and offer a test to a segment of the population to gather the clinical data as well as the economic data to build the case for the insurance company to cover the test. . . . Now, that's stuff we can just plug the GRAIL, you know, work into and accelerate the adoption of GRAIL, so there's a lot of work we can do on market access. . . . our teams have deep experience, nearing now a decade, on working with regulators to get cleared tests and to get cleared sequencers. We're working that in oncology now and we're working that for genetic disease now and hope to get the first – you know, to progress that as well." (deSouza (Illumina) Tr. 2343–44.)

Response to Finding No. 1133.1

The proposed finding is vague, confusing, unclear, incorrect, misleading, against the weight of the evidence, unreliable, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "deep expertise," "innovate programs," "contribute resources," "just plug the GRAIL . . . work into," "accelerate the adoption," "a lot of work we can do," "deep experience," and "hope to get the first . . . progress that as well." For similar reasons, the proposed finding is confusing. It is absolutely unclear how "that's stuff [Illumina] can just plug the GRAIL, you know, work into and accelerate the adoption of GRAIL." It's unclear what "stuff" Mr. deSouza is discussing, and it is equally unclear how Illumina would "plug the GRAIL, you know, work into" the "stuff" to "accelerate the adoption of GRAIL."

[redacted]

[redacted]

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

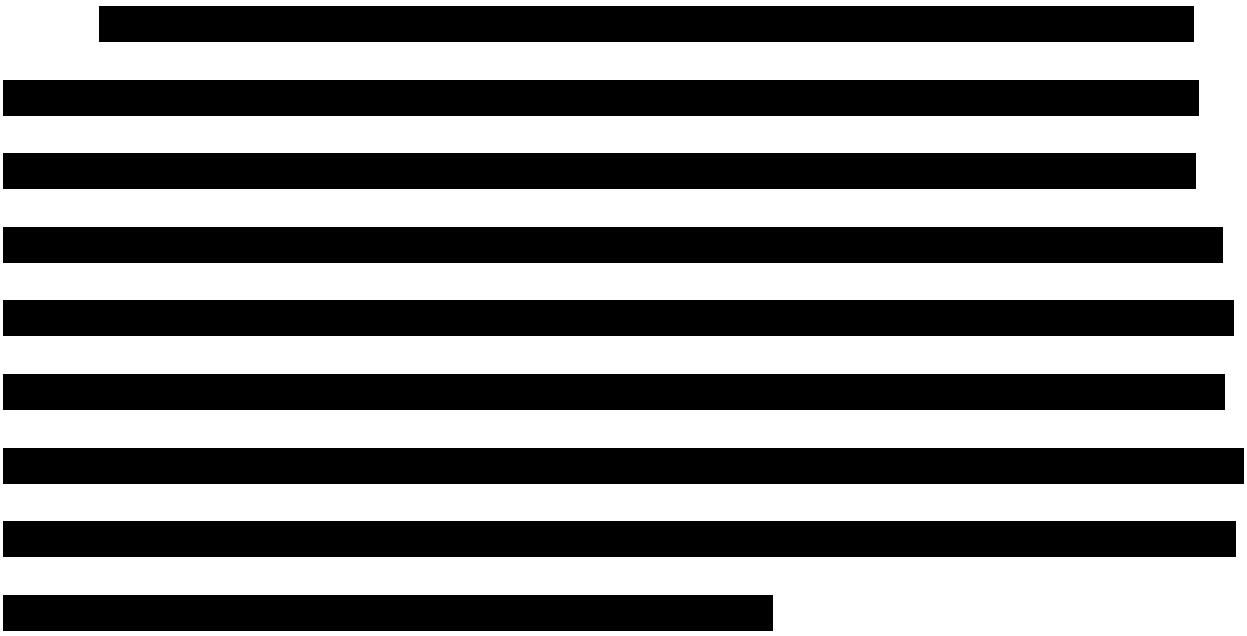
> 1133.2 Dr. Aravanis, Chief Technology Officer at Illumina and former head of R&D at GRAIL, testified that: "Illumina has made applications and has multiple pending applications for first-in-kind products for next-generation sequencing. In doing that, it's broken new ground working with the FDA on how to develop applications for these types of processes. They're very complex diagnostics. The applications are complex, and it's learned a tremendous amount in doing that and incorporated those into the current

processes and templates for making applications. Those benefits will be conferred to GRAIL as part of the acquisition" and that Illumina's plan is "[to] apply the same approaches that Illumina used in other areas where it's increased market access and reimbursement." (Aravanis (Illumina) Tr. 1945, 1948.)

Response to Finding No. 1133.2

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define and/or quantify the terms "made applications," "multiple pending applications," "broken new ground," "these types of processes," "very complex," "complex," "it's," "tremendous amount," "incorporated those," "the current processes and templates," "[t]hose benefits," "the same approaches," "other areas," "increase market access and reimbursement."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.



1133.3 Dr. Febbo, Chief Medical Officer at Illumina, testified that "I've seen our regulatory team. I've seen our broad teams come together to address multiple challenges, regulatory challenges as well as others. I know the incredible depth – how the incredible depth of expertise we have at Illumina is brought to bear and how we can motivate and really engage and execute on strategies to address challenges and to accelerate those timelines. . . . We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year". (Febbo (Illumina) Tr. 4345–46, 4360.)

Response to Finding No. 1133.3

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define and/or quantify the terms "broad teams," "multiple challenges," "incredible depth of expertise," "really engage," "execute on strategies," "accelerate those timelines," "[w]e," "in aggregate," "these efficiencies," "accelerate the adoption," "accelerate the . . . availability," and "approximately at least one year."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted]

[redacted]

1133.4 Ammar Qadan, Vice President and Head of Market Access at Illumina, testified that "[t]hrough some of the partnerships that we have today, we will be able to accelerate the development, for example, with commercial payers in the U.S. We – in fact, we can do a lot. We can also accelerate, though it's not my area of expertise, but we can accelerate hopefully the regulatory approval, resulting in an accelerated path for CMS coverage and reimbursement." (Qadan (Illumina) Tr. 4158–59.)

Response to Finding No. 1133.4

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define and/or quantify the terms "some of the partnerships," "accelerate the development . . . with commercial payers," "can do a lot," "accelerate," and "hopefully." The proposed finding is also unreliable, for similar reasons. If regulatory approval is "not [Mr. Qadan's] area of expertise," it is unclear what basis or foundation he has to discuss whether Illumina "can accelerate hopefully the regulatory approval" of Galleri.

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted]

[redacted]

1133.5 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that Illumina "has the ability to accelerate the adoption of this test or the approval of the test through the FDA. We also have the ability, because of the size and scope of the company, to establish reimbursement much more quickly than GRAIL would have the ability to do." (Flatley (Illumina) Tr. 4082.)

Response to Finding No. 1133.5

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define and/or quantify the terms "accelerate the adoption," "the size and scope of the company," "establish reimbursement," and "much more quickly."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted]

[redacted]

1133.6 Hans Bishop, Chief Executive Officer at GRAIL, testified that "deep expertise in interacting with regulators derisks and maybe speeds up the speed at which we can get the regulatory approvals, which are often – certainly that's true in the United States – a prerequisite to getting reimbursement. . . . [W]e have to be concerned about government and payers' ability to pay, and being part of Illumina will help us accelerate the speed at which we can drop the price of our tests." (Bishop (GRAIL) Tr. 1417.)

Response to Finding No. 1133.6

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define and/or quantify the terms "accelerate the adoption," "the size and scope of the company," "establish reimbursement," and "much more quickly."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted]

[redacted]

1133.7 [redacted]

Response to Finding No. 1133.7

[redacted]

[redacted]

- [redacted]

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- [redacted]
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- [redacted]

[redacted]

[redacted]

[redacted]

1133.8 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "a large inflection point to creating value and saving lives is going to be getting broad

> reimbursement. And this population we're addressing is between 50 and 80, of which, you know, the majority – a lot of those people are on public government pay, whether it's Medicare or something else. So to go down that path we'd have to have a PMA and get reimbursement, and so on. You know, Illumina has those resources to do those things and have demonstrated doing it in the past." (Freidin (GRAIL) Tr. 2980.)

Response to Finding No. 1133.8

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define and/or quantify the terms "large inflection point," "broad reimbursement," "a lot of those people," "public government pay," "that path," "those resources," "those things," "doing it," and "in the past." Moreover, Mr. Freidin is a Senior Vice President at Grail. He does not have basis or foundation to express an opinion regarding whether "Illumina has those resources to do those things," and whether Illumina "[has] demonstrated doing it in the past."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of a Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted]

[redacted]

1133.9 [redacted]

Response to Finding No. 1133.9

[redacted]

[redacted]

1133.10 [redacted]

Response to Finding No. 1133.10

[redacted]

1133.11 Mr. Qadan provided further information regarding the ways in which Illumina can accelerate market access for Galleri.

Response to Finding No. 1133.11

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

[redacted]

[redacted]

1133.12 Illumina has developed a plan to achieve the acceleration of market access. "[I]n the U.S., we will be working on accelerating CMS approval through clinical utility data and through accelerating the regulatory approval . . . Outside the U.S., there will be a lot of work needed with single-payer healthcare systems and countries, like what we have done, for example, with Genomics England, like what we have done with Germany, to accelerate the availability of Galleri in Europe, and third, as I mentioned, also the work that we can do in China to accelerate the availability of Galleri in China considering that there is a favorable environment in China for lab-developed tests now that did not exist before. So there are many things. Our group's experience then based on what we have done so far and the expertise we have developed, we can take many of

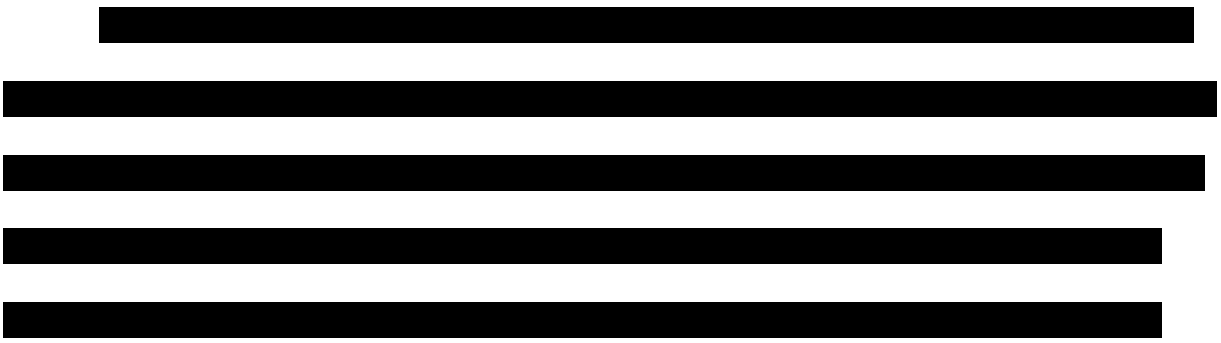
those initiatives to accelerate Galleri's availability and reimbursement in the different markets." (Qadan (Illumina) Tr. 4163.)

Response to Finding No. 1133.12

The proposed finding is confusing, circular, vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. Respondents' finding claims that Illumina's "plan to achieve . . . acceleration," includes "working on accelerating CMS approval[,] . . . work needed . . . to accelerate the availability of Galleri in Europe, and . . . work that [Illumina] can do in China to accelerate the availability of Galleri." (Qadan (Illumina) Tr. 4163). In essence, Respondents "plan to achieve the acceleration" is simply to accelerate Galleri—an entirely circular statement, for which Respondents provide no details whatsoever.

The proposed finding is vague. Respondents fail to define and/or quantify the terms "acceleration of market access," "through clinical utility data," "through accelerating the regulatory approval," "a lot of work," "accelerate the availability," "favorable environment," "many things," "many of those initiatives," "accelerate," and "the different markets."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.



[redacted]

1133.13 With regard to clinical utility, Mr. Qadan explained that Illumina has "a broad expertise in terms of developing those clinical studies, whether it is real-world data, as what we have just described with NIPT, the work that we're doing with whole genome sequencing, or even developing data from scratch like the work that we have done with NICUSeq study, which is double-blinded type of study, so more complicated. So we have experience building real-world data, we have experience building sophisticated clinical trials, and we have relationships, whether with healthcare systems or with payers, that would enable us to do both things as well."

Response to Finding No. 1133.13

The proposed finding is uncited, improper, vague, misleading, against the weight of the evidence, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings

of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the terms "a broad expertise," "those clinical studies," "as what we have just described with NIPT," "developing data from scratch," "double-blind type of study," "more complicated," "sophisticated clinical trials," and "both things."

[redacted].

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1133.14 With regard to economic utility, Mr. Qadan explained that Illumina could use its experience to help assess budget impacts and also help in "finding innovative partnerships that would enable us to gather data for the test that will inform the clinical utility of the test". (Qadan (Illumina) Tr. 4157.)

Response to Finding No. 1133.14

The proposed finding is vague, misleading, against the weight of the evidence, unreliable, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "economic utility," "its experience," "budget impacts," and "innovative partnerships."

[redacted]

[redacted]

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

> 1133.15 Illumina also plans to leverage the use of Galleri as a diagnostic aid to cancer ("DAC") in order to increase payer confidence and adoption of Galleri in the general population. As Mr. Qadan explained: "So diagnostic aid to cancer is one of the applications of Galleri, so it's the same test, Galleri. However, it is the use of Galleri in patients who could have started developing signs and symptoms of cancer. Because the test performs better in more advanced disease, we can expect the test to perform better in those patients. The value of this is that the clinical utility will be ruling out or ruling in whether those patients have cancer so that they do not go into multiple other tests and then they can hopefully start therapies. And the second is, there could be cost savings for the system to do one test that rules out or rules in cancer rather than multiple tests initially. So as we know payers around clinical utility and economic utility, there is clinical utility for DAC, and the economic utility could be even cost saving. So that will initially enable us to introduce Galleri into the marketplace while not having a huge budget impact for payers to resist. Through that entry, we can go into phase two, which is

> developing the data around the risk factors associated with those patients who tend to be positive for cancer, what do they share in common. And so that data will enable us then to go back and expand the use of Galleri in those patients with those risk factors to screen them first, so that will then expand the use of Galleri with an acceptable budget impact hopefully. And then the third phase hopefully will be once all of the clinical utility studies that GRAIL is doing or we will be doing start reporting results, that then can expand the use of Galleri in the general population above the age of 50, so it's a phasing of the Galleri budget impact knowing that payers might resist a test with high budget impact, so that's our plan." (Qadan (Illumina) Tr. 4163–64.)

Response to Finding No. 1133.15

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "plans," "leverage," "increase payer confidence," "performs better," "more advanced disease," "could be cost savings," "multiple other tests," "hopefully start therapies," "could be cost savings," "multiple tests initially," "could be even cost saving," "huge budget impact," "tend to be positive for cancer," "acceptable budget impact hopefully," "third phase hopefully," "all of the clinical utility studies that GRAIL is doing or we will be doing," "payers might resist," and "high budget impact."

And, rather than referencing pre-acquisition, ordinary course documents, Respondents cite only to the unfounded, self-serving testimony of an Illumina executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted]

[redacted]

1133.16 [redacted]

Response to Finding No. 1133.16

[redacted]

[redacted]

[redacted]

1133.17 [redacted]

Response to Finding No. 1133.17

[redacted]

[redacted]

[redacted]

1133.18 [redacted]

Response to Finding No. 1133.18

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[redacted]

1133.19 [redacted]

Response to Finding No. 1133.19

[redacted]

[redacted]

[redacted]

1133.20 [redacted]

Response to Finding No. 1133.20

[redacted]

[redacted]

[redacted]

1133.21 As Mr. Qadan further explained "in Europe we can work with single-payer systems and health technology assessment agencies to start understanding their needs to deliver on their needs, the same thing in countries like Australia and Japan. And then in a major market like China, we could start some of the work around patient or people willingness to pay for screening, for cancer screening, types of studies that can inform Galleri's launch. So we can work on all of that and hopefully, you know, accelerate Galleri launch in all of those countries." ([redacted] 4158–59; [redacted]

Response to Finding No. 1133.21

[redacted]

[redacted]

[redacted]

1133.22 Complaint Counsel did not present any contrary fact witness testimony and none of its experts are qualified to address the subject. (*See* [redacted]; PX7139 (Navathe Trial Dep. at 97–103); PX7140 (Rothman Trial Dep. at 42–44).)

Response to Finding No. 1133.22

[redacted]

[redacted]

1133.23 Echoing the unrefuted fact testimony, Dr. Deverka testified that the reunion of Illumina and GRAIL will accelerate GRAIL's FDA approval, CMS coverage and payor coverage. (RX6001 (Deverka Trial Dep. at 62–64).)

Response to Finding No. 1133.23

The proposed finding is incorrect, misleading, and should be disregarded by this Court. First, the proposed finding is incorrect because the "fact testimony" is not unrefuted. Complaint Counsel's post-trial brief, proposed findings of fact, and reply brief clearly refute Respondents' unsubstantiated efficiencies claims and demonstrate that Respondents' efficiencies claims are not cognizable nor can they justify the likely harm to competition from the Transaction. (CCFF Sec. VIII(C); Complaint Counsel's Post-Trial Brief at Section II(F)(2); Complaint Counsel's Post-Trial Reply Brief at Section V.). Second, the proposed finding is misleading because Dr. Deverka is not qualified to express any opinion regarding Respondents' claim that the Transaction will accelerate FDA approval. She has said as much in her deposition and trial deposition testimony. (*See, e.g.,* RX6001 (Deverka Trial Dep. 126) (Q. You're not an FDA expert. A. No.). Moreover, Respondents have not offered her to give such opinions. (RX6001 (Deverka Trial Dep. 25) ("[R]espondents offer Dr. Deverka as an expert concerning the evidence requirements to support payer decision-making for new genomics-based technologies, including

how companies can drive development of such evidence and accelerate market access for new genomics-based technologies). Here, Dr. Deverka is unqualified to offer any opinion regarding the acceleration of FDA approval, she has not been proffered by Respondents to do so, and therefore this proposed finding is improper and should be disregarded by this Court.

> 1133.24 Specifically, Dr. Deverka testified that Illumina's relationships with health systems and payors, its knowledge of payor evidence expectations and its ability to invest in large prospective studies that can be replicated across settings contribute and that "the acquisition will accelerate market access for Galleri." (RX6001 (Deverka Trial Dep. at 62–64).)

Response to Finding No. 1133.24

The proposed finding is vague, confusing, and should be disregarded by this Court. The proposed finding is vague. Respondents do not define the term "contribute" or "accelerate market access." The proposed finding is also confusing. Respondents say Dr. Deverka testified "Illumina's relationships[,] . . . knowledge[, and] . . . ability . . . contribute," but Respondents do not say what these things contribute to. Therefore, this Court should disregard the proposed finding.

The proposed finding is misleading insofar as it implies that Illumina would accelerate the "market access" of Galleri or that, based on the evidence offered by Respondents about the claimed acceleration, it constitutes a cognizable efficiency. [redacted]

[redacted]

Moreover, a cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." Horizontal Merger Guidelines § 10; see also Hackensack, 2022 WL 840463, at *10-11; Heinz, 246 F.3d at 720; FTC v. Staples, Inc., 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); Sysco, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." Otto Bock, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing H&R Block, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in H&R Block explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." H&R Block, 833 F. Supp. 2d at 90. Therefore, this Court should disregard the proposed finding.

> 1133.25 In addition, "if Illumina's resources and prior experience dealing with the FDA are brought to bear with the merged companies that I predict that the – that could accelerate regulatory approval for Galleri, which would then have the downstream impact of further accelerating payer and Medicare coverage." (RX6001 (Deverka Trial Dep. at 81); RX3867 (Deverka Expert Report) ¶ 121 (noting Illumina's "experienced regulatory and quality teams that can work to accelerate FDA and other approvals").)

Response to Finding No. 1133.25

The proposed finding is misleading because Dr. Deverka did not testify that the Transaction "will accelerate GRAIL's FDA approval." Dr. Deverka is not qualified to express

any opinion regarding Respondents' claim that the Transaction will accelerate FDA approval. She has said as much in her deposition and trial deposition testimony. (*See, e.g.*, RX6001 (Deverka Trial Dep. 126) (Q. You're not an FDA expert. A. No.). Moreover, Respondents have not offered her to give such opinions. (RX6001 (Deverka Trial Dep. 25) ("[R]espondents offer Dr. Deverka as an expert concerning the evidence requirements to support payer decision-making for new genomics-based technologies, including how companies can drive development of such evidence and accelerate market access for new genomics-based technologies). Here, Dr. Deverka is unqualified to offer any opinion regarding the acceleration of FDA approval, she has not been proffered by Respondents to do so, and therefore this proposed finding is improper and should be disregarded by this Court.

[redacted]

The proposed finding is vague. Respondents fail to define the terms "resources," "prior experience," "brought to bear," "the merged companies," "could accelerate regulatory approval,"

"downstream impact," and "further accelerating." Therefore, this Court should disregard the proposed finding.

1133.26 The following table compares GRAIL's and Illumina's capabilities in relevant responses and summarizes how the reunion of the companies will accelerate FDA, CMS and private payor coverage:

Table 12

Capability	GRAIL	Illumina	Expected Efficiencies
Dedicated staff	[redacted]	13 focused on market access; 18 in medical affairs; 17 in clinical affairs; 23 in regulatory affairs; 11 in biostatistics	[redacted]
Experience with private and public payors	[redacted]	Extensive and international. Established coverage track record for multiple NGS test categories (not in CA screening tests)	[redacted]
Health system partnerships	[redacted]	Extensive and international. Track record of success with NIPT, CGP and RUGD	[redacted]
De-risking of reimbursement challenges	[redacted]	Harvard Pilgrim/NIPT case Harvard Pilgrim/WGS case Queensland Australia WGS for RUGD case	[redacted]
Regulatory experience with PMA	[redacted]	Extensive	[redacted]

Capability	GRAIL	Illumina	Expected Efficiencies
			[redacted]
Distributed version of test (requires FDA/regulatory approval)	[redacted]	Area of established expertise for Illumina	[redacted]
Global presence and expertise	[redacted]	Extensive	[redacted]
Resources to support appropriate real-world use of Galleri, fit into clinical workflow	[redacted]	Experience with educating patients and providers through pre-competitive collaborations (CAPS). Existing partnership with Genome Medical providing education to individuals, health care providers, and employers nationwide	[redacted]
Value assessment methods development	[redacted]	Experience with funding methods research for value assessments of NGS-based tests (GEECS)	[redacted]
Technical solutions such as process efficiencies working with laboratories, supply chains and automation	[redacted]	Extensive	[redacted]

(RX3867 (Deverka Expert Report) ¶ 112 n.217; RX6001 (Deverka Trial Dep. at 64–86) (explaining how each of the factors in the above table contribute to Illumina's ability to accelerate Galleri).)

Response to Finding No. 1133.26

[redacted]

[redacted]

[redacted]

1134. The evidence of regulatory and market access efficiencies is essentially unrefuted.

Response to Finding No. 1134

The proposed finding is uncited, improper, vague, misleading, against the weight of the evidence, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings

of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the term "essentially unrefuted."

The proposed finding is misleading. Respondents' evidence of their claimed regulatory and market access efficiencies is not "essentially unrefuted." It is heavily refuted. Complaint Counsel's post-trial brief, proposed findings of fact, and reply brief clearly refute Respondents' unsubstantiated efficiencies claims and demonstrate that Respondents' efficiencies claims are not cognizable nor can they justify the likely harm to competition from the Transaction. (CCFF Sec. VIII(C); Complaint Counsel's Post-Trial Brief at Section II(F)(2); Complaint Counsel's Post-Trial Reply Brief at Section V.). To suggest that "[t]he evidence of regulatory and market access efficiencies is essentially unrefuted," is disingenuous, at best. Therefore, this Court should disregard the proposed finding.

1134.1 Complaint Counsel does not dispute that GRAIL is far from being widely available.

Response to Finding No. 1134.1

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents do not define the terms "far from" and

"widely available." Therefore, this Court should disregard the proposed finding.

1134.2 Nor does Complaint Counsel dispute that GRAIL has limited regulatory and market access capabilities.

Response to Finding No. 1134.2

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the terms "limited regulatory . . . capabilities" and "limited . . . market access capabilities." Notwithstanding Respondents' vague term, the proposed finding is misleading. [redacted] Therefore, this Court should disregard the proposed finding.

> 1134.3 Instead, it relies on the testimony of two purported experts, Dr. Rothman and Dr. Navathe, for the proposition that Illumina's ability to accelerate Galleri is not properly substantiated.

Response to Finding No. 1134.3

The proposed finding is uncited, improper, vague, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the terms "it," "purported experts," "ability to accelerate," and "properly substantiated." What is more insofar as Complaint Counsel does rely on Dr. Rothman and Dr. Navathe, the proposed finding is misleading because Complaint Counsel does not simply rely "on the testimony" of these experts. Both experts submitted reports concerning the efficiencies claimed in the proposed matter, as well as providing discovery and trial deposition testimony. Therefore, this Court should disregard the proposed finding.

> 1134.4 However, neither Dr. Rothman nor Dr. Navathe has relevant expertise to assess these efficiencies. (PX7139 (Navathe Trial Dep. at 97–102) (admitting that he lacks expertise in seeking FDA approval for an MCED test, how the FDA will evaluate an MCED test, seeking payor coverage for an MCED test and how payors will evaluate an MCED test); PX7140 (Rothman Trial Dep. at 42–46) (admitting that he lacks expertise with respect to FDA approval or payor reimbursement).)

Response to Finding No. 1134.4

The proposed finding is not a fact, but rather a legal conclusion, and it should be disregarded by this Court. It is the purview of this Court to determine whether Dr. Rothman and Dr. Navathe have "relevant expertise." To be sure, Dr. Rothman and Dr. Navathe *do* have

relevant expertise, as evidenced by their qualifications discussed in their expert reports and trial depositions. (*See, e.g.*, PX7139 (Navathe Trial Dep. at 6-19; PX7140 (Rothman Trial Dep. at 6-11)). Therefore, this Court should disregard the proposed finding.

> 1134.5 Dr. Navathe also made clear that he does not have an opinion on the expected timing of Galleri with or without the Transaction and that he had no opinion on acceleration. (PX7139 (Navathe Trial Dep. at 130, 132) (testifying that he "would not be able to predict timing" and has not drawn any conclusion of his own as to when Galleri is likely to get FDA approval with or without the Transaction).)

Response to Finding No. 1134.5

The proposed finding is vague and should be disregarded by this Court. Respondents fail to define the terms "expected timing" and "acceleration." Respondents have not provided any information with respect to "expected timing," particularly "with . . . the Transaction," and so it is no wonder that Dr. Navathe "would not be able to predict timing"—Respondents have not offered any information to facilitate such a prediction and do not offer a prediction themselves.

> 1134.6 Moreover, neither Dr. Navathe nor Dr. Rothman attempts to undermine the undisputed testimony (described above).

Response to Finding No. 1134.6

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the term "the undisputed testimony (described above)." There are thousands of findings "above" this proposed finding. Respondents proposed finding is vague and this Court should disregard the proposed evidence.

The proposed finding is also confusing. Both Dr. Rothman and Dr. Navathe are rebuttal experts. As such, they are limited—per this Court's Order—to rebutting the contents of Respondents' experts' reports. (*See* Scheduling Order at 9). As Respondents' expert reports were submitted before trial, it is befuddling that Respondents would expect Drs. Rothman or Navathe to address any trial testimony in their rebuttal reports.

Nonetheless, Drs. Rothman and Navathe do undermine the substance of the "testimony (described above)." Dr. Rothman found, among other things, that Respondents' experts' claimed acceleration efficiency is not a cognizable efficiency. (CCFF ¶ 5033). Dr. Navathe found, among other things, that [redacted] (CCFF ¶¶ 5163). Therefore, this Court should disregard the proposed finding.

1134.7 [redacted]

Response to Finding No. 1134.7

[redacted]

[redacted]

1134.8 Moreover, unrefuted fact witness testimony (presented at trial) shows Illumina will benefit from acceleration (PX5027 (Illumina) at 36 (noting that a potential transaction would both accelerate adoption of screening market and increase share of revenue)), and that Illumina intends to implement plans to accelerate Galleri (*see e.g.* deSouza (Illumina) Tr. 2343–44). The government's experts ignored this testimony altogether.

Response to Finding No. 1134.8

The last sentence of proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is misleading. Respondents' "fact witness testimony (presented at trial)" is not "unrefuted." It is heavily refuted. Complaint Counsel's post-trial brief, proposed findings of fact, and reply brief clearly refute Respondents' unsubstantiated efficiencies claims and demonstrate that Respondents' efficiencies claims are not cognizable nor can they justify the likely harm to competition from the Transaction. (CCFF Sec. VIII(C); Complaint Counsel's

Post-Trial Brief at Section II(F)(2); Complaint Counsel's Post-Trial Reply Brief at Section V.). To suggest that the "fact witness testimony (presented at trial)" is "unrefuted," is disingenuous, at best.

The proposed finding is confusing, as it claims "unrefuted fact witness testimony" will show something, but then cites to a business document. In the cited testimony of Mr. deSouza, he does not testify that "Illumina intends to implement plans to accelerate Galleri." He lists, in relevant part, "stuff that we [Illumina] can just plug the GRAIL, you know, work into and accelerate the adoption of GRAIL." He does not list any plans. He does not evidence any intentions. He simply provided self-serving testimony, uncorroborated by any ordinary course documents or other evidence.

Lastly, the proposed finding is vague. Respondents fail to define and/or quantify the terms "benefit," "acceleration," "accelerate," and "the government's experts." Drs. Scott Morton, Rothman, and Navathe submitted their report to this Court before the trial began, and it is unclear why Respondents expect their reports to address trial testimony that had not occurred when they submitted their reports. Moreover, to the extent Respondents mean Drs. Rothman and Navathe by "the government's experts," both are rebuttal experts. As such, they are limited—per this Court's Order—to rebutting the contents of Respondents' experts' reports. (*See* Scheduling Order at 9). As Respondents' expert reports were submitted before trial, it is befuddling that Respondents would expect Drs. Rothman or Navathe to address any trial testimony. Therefore, this Court should disregard the proposed finding.

1134.9 [redacted] However, speculation regarding future legislation does nothing to undermine the acceleration Illumina can create today, and Dr. Navathe pointed to no evidence that the potential legislation would actually benefit GRAIL in the same ways the Transaction would.

Response to Finding No. 1134.9

The last sentence of the proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

[redacted]

Moreover, a cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90. Therefore, this Court should disregard the proposed finding.

1135. Illumina's fact and expert witnesses provided detailed testimony regarding Illumina's plans to accelerate Galleri's regulatory approval.

Response to Finding No. 1135

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

The proposed finding is vague. Respondents fail to define the term "detailed testimony."

[redacted]

Moreover, a cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. For example, the "verifiability" prong requires Respondents to show "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency. . . ." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). But Respondents only rely on vague claims—unsupported by ordinary course documents—from their business executives about purported benefits of the Transaction. As the court in *H&R Block* explained, "[w]hile reliance on the estimation and judgment of experienced executives about costs may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis resulting in the cost estimates renders them not cognizable by the Court." *H&R Block*, 833 F. Supp. 2d at 90. Therefore, this Court should disregard the proposed finding.

C. Reuniting Illumina and GRAIL Will Lead to R&D Efficiencies

1136. In addition to accelerating market access, the Transaction will lead to significant R&D efficiencies, through the combination of GRAIL's expertise in methylation, data science and software development and Illumina's complementary expertise in sequencing and bioinformatics. (deSouza (Illumina) Tr. 2355–56; Aravanis (Illumina) Tr. 1952–54; Febbo (Illumina) Tr. 4356–60; Flatley (Illumina) Tr. 4082, 4088–89; Bishop (GRAIL) Tr. 1416; Jamshidi (GRAIL) Tr. 4048, [redacted].)

Response to Finding No. 1136

The proposed finding is vague because it does not define "accelerating market access," "significant," "R&D efficiencies," "expertise," or "complementary." The proposed finding is confusing because it does not explain how or why combining Illumina's "expertise" in sequencing and bioinformatics with Grail's "complementary" "expertise" in methylation, etc., would generate *any* "R&D efficiencies." It should therefore be disregarded.

The proposed finding presents a factual conclusion—that "the Transaction will lead to significant R&D efficiencies"—which is misleading and incomplete. This conclusory statement about the factual record misrepresents the weight of the evidence, in so doing relying only on the self-serving testimony of its executives. Respondents failed to demonstrate any cognizable R&D efficiencies; none of Respondents' claims survive scrutiny.

1137. Respondents presented extensive fact testimony in support of this efficiency, whereas Complaint Counsel presented no fact witness to refute it. (deSouza (Illumina) Tr. 2355–56; Aravanis (Illumina) Tr. 1952–54; Febbo (Illumina) Tr. 4356–60; Flatley (Illumina) Tr. 4082, 4088–89; Bishop (GRAIL) Tr. 1416; [redacted].)

Response to Finding No. 1137

The proposed finding is vague because it does not define "extensive." The proposed finding presents a factual conclusion—that Respondents "presented extensive fact testimony . . . [and] Complaint Counsel presented no fact witness to refute it"—which is misleading and incomplete.

The proposed finding is misleading and incomplete, and it should be disregarded. The "extensive fact testimony" cited amounts to a handful of generalities and vague statements about

how Illumina will accelerate Grail's R&D with no specifics. For example, in Mr. deSouza's testimony, his explanation for why Illumina could "create R&D efficiencies" was that Illumina has been "running genomic tests" and that Illumina's "R&D teams are very good optimizing" running samples. When asked on direct to "[g]ive us some examples . . . of the kinds of R&D efficiencies that the transaction will create independent of the Galleri test," Mr. deSouza responds, "We believe that . . . we will bring our R&D teams together and immediately start the work [for non-MCED applications]. We believe – we will get the teams working on it, and we would love to get a blood test for those conditions in addition to this cancer screen." In other words, Mr. deSouza's testimony amounts to saying Illumina has smart employees. That does not amount to "extensive" merger-specific R&D efficiencies. Dr. Aravanis's testimony is no more convincing. He explains that Illumina could improve the Galleri workflow, which he states could be accomplished if Grail "share[d], you know, information on its assay, so all of the chemistries, the materials in it, the protocol. It would also require it to share with us all of its software and bioinformatics." He suggests that is impossible to share the information without the Acquisition, ignoring the fact that [redacted]

The proposed finding is misleading to the extent it suggests Complaint Counsel does not dispute Respondents claims about R&D efficiencies. Indeed, documents, testimony, and expert opinion evidence refute Respondents' vague assertions of R&D efficiencies. (*See* CCFF ¶¶ 5721-56). For example, [redacted]

[redacted] In addition, the fact that Illumina spun out Grail because it was unwilling to make the requisite significant investments in MCED testing R&D shows that Respondents' assertions about Illumina's commitment to R&D are made-for-litigation claims. (*See* CCFF ¶¶ 50-54) (Illumina relinquished control of Grail because its board determined that its shareholders would not have tolerated the magnitude of Illumina's earnings dilution from Grail R&D and clinical trial spending without corresponding revenues.).

1138. GRAIL is a relatively small company without the resources to focus on all of the R&D projects that it might otherwise be interested in pursuing. (Flatley (Illumina) Tr. 4088 ("GRAIL is a company with much more limited resources than what Illumina has, and as such, they were appropriately focused on delivering the Galleri test to the market and getting that as advanced as they possibly could"); Bishop (GRAIL) Tr. 1367 ("The investments we need to continue to make in R&D continue to be very significant."); [redacted]

Response to Finding No. 1138

The proposed finding is vague because it does not define "relatively small," "resources," "all of the R&D projects, or "pursuing."

The proposed finding is misleading and incomplete, and it should be disregarded. Respondents do not allege that Grail is short of funds or unable to attract investment to support its R&D investment. To the contrary, prior to the Acquisition [redacted]

[redacted]

1139. Illumina is a larger company with the financial resources to focus on R&D. (Flatley (Illumina) Tr. 4088.)

Response to Finding No. 1139

The proposed finding is vague, confusing, misleading, and incomplete. It should therefore be disregarded. The proposed finding is vague because it does not define "larger," "financial resources," or "focus." The proposed finding is confusing because it does not explain what Illumina is "larger" than or why being "large[]" suggests it can focus on R&D. In fact, Illumina's spinoff of Grail directly contradicts this finding. Illumina spun out Grail because it was unwilling to make the requisite significant investments in MCED testing R&D shows that Respondents' assertions about Illumina's commitment to R&D are made-for-litigation claims. (*See* CCFF ¶¶ 50-54) (Illumina relinquished control of Grail because its board determined that its shareholders would not have tolerated the magnitude of Illumina's earnings dilution from Grail R&D and clinical trial spending without corresponding revenues.).

The proposed finding is misleading and incomplete because it assumes Grail does not have the financial resources to focus on R&D without the Acquisition. But Respondents do not allege that Grail is short of funds or unable to attract investment to support its R&D investment. To the contrary, prior to the Acquisition [redacted]

[redacted]

1139.1 In fact, R&D is a core component of Illumina's business. (Aravanis (Illumina) Tr. 1948 ("At Illumina, you know, innovation is incredibly important to the company, and we invest tremendously in research and development."); deSouza (Illumina) Tr. 2353 ("Q. . . . What role does R&D play in Illumina's business generally? A. R&D is absolutely critical at Illumina. Q. Why is that? A. We believe that innovation is going to be critical to, you know, unlock the future markets for genomics, that to unlock the next set of markets we need to continue to deliver lower prices into the market."); Aravanis (Illumina) Tr. 1950 ("[O]f the approximately 1800 people in the core research and development group at Illumina, about a quarter of those, you know, close to 500, have advanced scientific or advanced engineering degrees.").)

Response to Finding No. 1139.1

The proposed finding is vague because it does not define "R&D," "core component," or "business." Moreover, the proposed finding is confusing because it appears to discuss the alleged importance of *sequencing* R&D and it is unclear how that is relevant to MCED testing. It should therefore be disregarded.

The proposed finding is misleading and incomplete to the extent it suggests—without basis—that Illumina's sequencing R&D team will somehow accelerate R&D discoveries for Grail's MCED tests. It is also unclear why the claim that "innovation is incredibly important" or

that 500 out of 1800 people in the "core research and development group at Illumina" "have advanced scientific or advanced engineering degrees" suggests a merger-specific R&D efficiency. Unless Respondents are claiming it is not the case that "innovation is incredibly important" at Grail, or that Grail does not have enough employees with advanced degrees, nothing about this proposed finding provides a merger-specific R&D efficiency.

Further, the proposed finding is misleading and incomplete because it mischaracterizes the importance of R&D at Illumina. Illumina's spinoff of Grail directly contradicts this finding. Illumina spun out Grail because it was unwilling to make the requisite significant investments in MCED testing R&D shows that Respondents' assertions about Illumina's commitment to R&D are made-for-litigation claims. (*See* CCFF ¶¶ 50-54) (Illumina relinquished control of Grail because its board determined that its shareholders would not have tolerated the magnitude of Illumina's earnings dilution from Grail R&D and clinical trial spending without corresponding revenues.).

> 1139.2 Illumina spends "over $600 million in R&D" annually "which is about twice as much as a percentage of our revenue on R&D as the industry average." (deSouza (Illumina) Tr. 2354.)

Response to Finding No. 1139.2

The proposed finding is vague because it does not define "R&D," "our revenue," or "the industry average." The proposed finding is confusing because it is unclear what bearing Illumina's existing R&D spend—presumably on NGS-related innovations—relative to other unnamed companies in "the industry" has on its ability to generate R&D efficiencies for MCED testing. It should therefore be disregarded.

The proposed finding is misleading and incomplete because it mischaracterizes the importance of R&D at Illumina. Illumina's spinoff of Grail directly contradicts this finding. Illumina spun out Grail because it was unwilling to make the requisite significant investments in

MCED testing R&D shows that Respondents' assertions about Illumina's commitment to R&D are made-for-litigation claims. (*See* CCFF ¶¶ 50-54) (Illumina relinquished control of Grail because its board determined that its shareholders would not have tolerated the magnitude of Illumina's earnings dilution from Grail R&D and clinical trial spending without corresponding revenues).

> 1139.3 Illumina has been widely recognized for its R&D work. (deSouza (Illumina) Tr. 2354 (Illumina has been "recognized as one of the hundred most influential companies by TIME. . . . MIT Technology Review recognized us as the number one smartest company in the world a while ago. So we've received a number of awards over the last few years for our R&D work."))

Response to Finding No. 1139.3

The proposed finding is vague because it does not define "widely recognized" or "R&D work." The proposed finding is unclear because it does not describe how TIME recognizing it as an "influential compan[y]" suggests anything about its R&D capabilities for MCED testing. So too with the MIT Technology review at one point naming Illumina one of the "smartest" companies. Without any information about the methodology or reasoning behind these awards they should be disregarded.

The proposed finding is misleading and incomplete because it mischaracterizes the importance of R&D at Illumina, particularly for MCED testing. In fact, Illumina's spinoff of Grail directly contradicts this finding. Illumina spun out Grail because it was unwilling to make the requisite significant investments in MCED testing R&D shows that Respondents' assertions about Illumina's commitment to R&D are made-for-litigation claims. (*See* CCFF ¶¶ 50-54) (Illumina relinquished control of Grail because its board determined that its shareholders would not have tolerated the magnitude of Illumina's earnings dilution from Grail R&D and clinical trial spending without corresponding revenues).

1140. The reunion of Illumina and GRAIL will lead to significant R&D efficiencies both related to the Galleri test and related to other technologies.

Response to Finding No. 1140

The proposed finding is unsupported because it cites no record evidence. It should therefore be disregarded.

1140.1 As Jay Flatley testified, "We had some opportunities in the R&D side, because when you put brilliant people together like we have at GRAIL and Illumina, sparks fly." (PX7079 (Flatley (Illumina) Dep. at 31).)

Response to Finding No. 1140.1

The proposed finding is misleading and incomplete and should be disregarded. The full quote describes a moment in which Illumina detected cancer when yielding false-positive NIPT tests for Down Syndrome. Illumina did something "absolutely unintended" to detect cancer in the blood. (PX7079 (Flatley (Illumina) Dep. at 31-38).) That is not probative of any verifiable merger-specific R&D efficiencies post-Acquisition.

Moreover, multiple other individuals were already exploring the potential use of cfDNA for an MCED test well before Illumina's acquisition of Verinata—well before the supposed "sparks" were "fly[ing]" at Illumina. For example, Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that could provide early detection of colon cancer. (CCFF ¶ 357.) In March 2009, Dr. Ahlquist told Exact's CEO, Kevin Conroy, of his vision for detecting many or most cancers from a simple blood draw. (CCFF ¶ 358.) Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (CCFF ¶ 358.) Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier, (CCFF ¶ 359), [redacted] At the same time Exact was working with Dr. Ahlquist on its MCED test,

Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (CCFF ¶ 361.) Dr. Vogelstein was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies," (CCFF ¶ 363), and he ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (CCFF ¶ 365.) Ultimately, Dr. Vogelstein became a co-founder of Thrive, (CCFF ¶ 366), and his discoveries led to the creation of Thrive's CancerSEEK MCED test. (CCFF ¶ 364.)

Claimed R&D efficiencies that Respondents contend will result from the Acquisition are novel discoveries and other scientific breakthroughs, which by definition cannot be identified with specification. Respondent does not—because it cannot—identify the specific breakthroughs, products, or benefits which may result, nor does Respondent identify the timing, likelihood, or cost to achieve such alleged benefits.

Respondents' corporate designee testifying about efficiencies conceded that "Illumina [had] not attempted to quantify these [claimed R&D efficiencies]," (CCFF ¶ 5735), as did Illumina's economic expert, who testified that he did not quantify the benefit of R&D efficiency, (CCFF ¶ 5727), did not attempt to estimate the scale of R&D efficiencies, (CCFF ¶ 5728), and did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (CCFF ¶ 5730). Indeed, Respondent's expert conceded in his deposition that "it's hard to make predictions as to exactly what R&D efficiencies would result," (CCFF ¶ 5729), and as such, he did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies, (CCFF ¶ 5731), or attempt to identify what specific products may result from the

claimed R&D efficiencies. (CCFF ¶ 5732). As Complaint Counsel's efficiency expert correctly concluded, [redacted]

1141. Illumina and GRAIL witnesses testified—without contradiction—that Galleri-specific efficiencies will arise from the reunion of Illumina and GRAIL.

Response to Finding No. 1141

The proposed finding cites no record evidence. It is unsupported and should therefore be disregarded. In addition, the claim that "Galleri-specific efficiencies" will arise from the Acquisition is "without contradiction" is misleading. Complaint Counsel has marshaled evidence to contradict such claims.

> 1141.1 Francis deSouza, Chief Executive Officer and President of Illumina, testified that: "Our team has deep experience over – over a decade now in optimizing workflows in the processing of genomic tests. We have been running genomic tests at scale for over a decade now. What that means is our R&D teams are very good at optimizing, you know, how samples come in, so sample accessioning, how samples are prepared for sequencing, so both the sample extraction as well as library preparation. And then our teams are very good at creating high-throughput bioinformatics pipelines to process the data, and so our teams are very good at creating lower-cost, high-throughput workflows to process samples, and that will benefit Galleri." (deSouza (Illumina) Tr. 2355–56.)

Response to Finding No. 1141.1

The proposed finding is misleading and incomplete and should be disregarded. The proposed finding suggests that Illumina's ability to improve its NGS platforms and "run[] genomic tests" somehow makes it uniquely capable of enhancing Grail's MCED testing (or other assay) R&D. The proposed finding does not explain how processing samples through NGS platforms gives Illumina MCED testing expertise.

Claimed R&D efficiencies that Respondents contend will result from the Acquisition are

novel discoveries and other scientific breakthroughs, which by definition cannot be identified with specification. Respondent does not—because it cannot—identify the specific breakthroughs, products, or benefits which may result, nor does Respondent identify the timing, likelihood, or cost to achieve such alleged benefits.

Respondent's corporate designee testifying about efficiencies conceded that "Illumina [had] not attempted to quantify these [claimed R&D efficiencies]," (CCFF ¶ 5735), as did Illumina's economic expert, who testified that he did not quantify the benefit of R&D efficiency, (CCFF ¶ 5727), did not attempt to estimate the scale of R&D efficiencies, (CCFF ¶ 5728), and did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (CCFF ¶ 5730). Indeed, Respondent's expert conceded in his deposition that "it's hard to make predictions as to exactly what R&D efficiencies would result," (CCFF ¶ 5729), and as such, he did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies, (CCFF ¶ 5731), or attempt to identify what specific products may result from the claimed R&D efficiencies. (CCFF ¶ 5732). As Complaint Counsel's efficiency expert correctly concluded, [redacted]

> 1141.2 Alex Aravanis, Chief Technology at Illumina and former head of R&D at GRAIL, testified that: "So Illumina is developing applications in multiple areas: noninvasive prenatal testing, genetic disease testing, therapy selection. We believe that some of those innovations that we're making in those other areas we will be able to apply also to future versions of the Galleri test, improving the performance and, therefore, increasing the clinical value of the test. Another type of R&D efficiency will be to lower the cost of the Galleri test faster. Illumina has significant experience and capabilities in miniaturizing assays, simplifying assays, developing new components for assays that can

> lower cost, internalizing manufacturing of expensive components, and by internalizing the manufacturing of them, reducing the cost of the overall test. Illumina can manufacture its own enzymes and, therefore, this makes the internalization and manufacturing at lower cost possible." (Aravanis (Illumina) Tr. 1952.)

Response to Finding No. 1141.2

The proposed finding is unsupported and should be disregarded. It is unclear how Illumina's development of tests outside of cancer screening could put Illumina in a unique position to "improve the performance" of Galleri or "lower the cost." The proposed finding provides no specifics of what "some of those innovations" are, why Dr. Aravanis "believe[s]" Illumina "will be able to apply [them] also to future versions of the Galleri test" or how those "innovations" from different areas could materialize into a better or lower cost MCED test.

Respondent's corporate designee testifying about efficiencies conceded that "Illumina [had] not attempted to quantify these [claimed R&D efficiencies]," (CCFF ¶ 5735), as did Illumina's economic expert, who testified that he did not quantify the benefit of R&D efficiency, (CCFF ¶ 5727), did not attempt to estimate the scale of R&D efficiencies, (CCFF ¶ 5728), and did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (CCFF ¶ 5730). Indeed, Respondent's expert conceded in his deposition that "it's hard to make predictions as to exactly what R&D efficiencies would result," (CCFF ¶ 5729), and as such, he did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies, (CCFF ¶ 5731), or attempt to identify what specific products may result from the claimed R&D efficiencies. (CCFF ¶ 5732). As Complaint Counsel's efficiency expert correctly concluded, [redacted]

[redacted]

1141.3 Phil Febbo, Chief Medical Officer at Illumina, testified that "Well, what I've seen and I'm excited about occurring as the companies come together is that as you expand your testing, as you scale testing and you test hundreds, thousands, tens of thousands of patients, you end up getting data that really helps you understand the test to a degree that's even deeper than initially. It also gives you data where you can bring in your biostatisticians and biostatistics reports to me, you can bring in your – you know, your – your medical experts, and together to work with your product development folks that is in core R&D under Alex Aravanis and look at those signals and look at how to improve the test itself, improve the performance, improve the efficiency." (Febbo (Illumina) Tr. 4356–57.)

Response to Finding No. 1141.3

The proposed finding is confusing and should be disregarded. It is unclear why the proposed finding indicates an R&D efficiency specific to Illumina's Acquisition of Grail when it appears to reference the sort of data gathering that would occur when Galleri "scale[s] testing" even absent the Acquisition.

The claimed R&D efficiencies that Respondents contend will result from the Acquisition are novel discoveries and other scientific breakthroughs, which by definition cannot be identified with specification. Respondent does not—because it cannot—identify the specific breakthroughs, products, or benefits which may result, nor does Respondent identify the timing, likelihood, or cost to achieve such alleged benefits.

Respondent's corporate designee testifying about efficiencies conceded that "Illumina [had] not attempted to quantify these [claimed R&D efficiencies]," (CCFF ¶ 5735), as did Illumina's economic expert, who testified that he did not quantify the benefit of R&D efficiency, (CCFF ¶ 5727), did not attempt to estimate the scale of R&D efficiencies, (CCFF ¶ 5728), and did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (CCFF ¶ 5730). Indeed, Respondent's expert conceded in his deposition that "it's hard to make predictions as to exactly what R&D

efficiencies would result," (CCFF ¶ 5729), and as such, he did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies, (CCFF ¶ 5731), or attempt to identify what specific products may result from the claimed R&D efficiencies. (CCFF ¶ 5732). As Complaint Counsel's efficiency expert correctly concluded, [redacted]

> 1141.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "we could take advantage of the data that's coming from the international expansion, integrate that data, and use the deep learning algorithms to improve the accuracy of the Galleri test and to improve the number of cancers that it – that it addresses. So we would accelerate the improvement of the Galleri test on the one hand. (Flatley (Illumina) Tr. 4082.)

Response to Finding No. 1141.4

It is unclear how Illumina's "data" that is "coming from the international expansion"—which is sufficiently vague as to be unverifiable—would put Illumina in a position to accelerate Grail's R&D for MCED testing. It is not clear what categories or types of data Illumina has generated, why "international expansion" data is useful, or how any of it would translate into Acquisition-specific benefits to Galleri. The proposed finding should therefore be disregarded.

The claimed R&D efficiencies that Respondents contend will result from the Acquisition are novel discoveries and other scientific breakthroughs, which by definition cannot be identified with specification. Respondent does not—because it cannot—identify the specific breakthroughs, products, or benefits which may result, nor does Respondent identify the timing, likelihood, or cost to achieve such alleged benefits.

Respondent's corporate designee testifying about efficiencies conceded that "Illumina

[had] not attempted to quantify these [claimed R&D efficiencies]," (CCFF ¶ 5735), as did Illumina's economic expert, who testified that he did not quantify the benefit of R&D efficiency, (CCFF ¶ 5727), did not attempt to estimate the scale of R&D efficiencies, (CCFF ¶ 5728), and did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (CCFF ¶ 5730). Indeed, Respondent's expert conceded in his deposition that "it's hard to make predictions as to exactly what R&D efficiencies would result," (CCFF ¶ 5729), and as such, he did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies, (CCFF ¶ 5731), or attempt to identify what specific products may result from the claimed R&D efficiencies. (CCFF ¶ 5732). As Complaint Counsel's efficiency expert correctly concluded, [redacted]

> 1141.5 Hans Bishop, then-Chief Executive Officer of GRAIL, testified that "ongoing access to funding is more secure as part of a large, successful, profitable company, and I believe that Illumina, as an outstanding technical innovation company, deeply understand[s] the importance of ongoing investment in research and development. That's how they've been successful, by continuing to do that. So I believe that the resources that we need to be reliably continuing to make those sorts of investments are greatly secured. I also believe that certain technical abilities that Illumina have will contribute to our performance in that area." (Bishop (GRAIL) Tr. 1416.)

Response to Finding No. 1141.5

The proposed finding is misleading to the extent it suggests Illumina's funding will somehow provide a merger-specific R&D efficiency for Grail. It should therefore be disregarded. There is no evidence that Illumina has any unique assets or experience that position it as the only company that could help Grail achieve such R&D advances. With respect to

financing, Grail would have been able to attain funding through less anticompetitive means than the Acquisition. For example, prior to the Acquisition, [redacted]

The fact that Illumina spun out Grail because it was unwilling to make the requisite significant investments in MCED testing R&D shows that Respondents' assertions about Illumina's commitment to R&D are made-for-litigation claims. (*See* CCFF ¶¶ 50-54) (Illumina relinquished control of Grail because its board determined that its shareholders would not have tolerated the magnitude of Illumina's earnings dilution from Grail R&D and clinical trial spending without corresponding revenues.).

1141.6 [redacted]

[redacted]

Response to Finding No. 1141.6

[redacted]

[redacted]

[redacted]

[redacted]

1141.7 Complaint Counsel did not even try to undermine this testimony through cross examination. It stands unrefuted.

Response to Finding No. 1141.17

The proposed finding is unsupported because it does not cite to anything in the factual record, including the "testimony" referenced that supposedly "stands unrefuted." It should therefore be disregarded.

The proposed finding misstates the record. Complaint Counsel did, in fact, undermine testimony relating to R&D efficiencies through cross examination. In addition, Complaint Counsel has presented evidence that undermines Respondents' efficiencies claims, as reflected in Complaint Counsel's responses to their proposed findings that actually cite to parts of the evidentiary record.

1142. Similarly, party witnesses have testified that the Transaction will generate a number of non-Galleri related R&D efficiencies.

Response to Finding No. 1142

The proposed finding is unsupported because it does not cite to anything in the factual record, including the "party witness[]" testimony that it references. The proposed finding should therefore be disregarded.

The proposed finding is irrelevant in that it suggests—without any concrete evidence—that the Acquisition will generate efficiencies outside of the relevant market. Respondents appear to make inappropriate attempts to justify their anticompetitive merger by asserting unsubstantiated efficiencies outside of the relevant market.

> 1142.1 Francis deSouza, Chief Executive Officer and President of Illumina, testified that: "We believe that – (inaudible) – once we – once we're allowed to merge, we will bring our R&D teams together and immediately start the work necessary to identify the genomic biomarkers in blood for other conditions, like fatty liver disease, neurological conditions like Alzheimer's and Parkinson's. We believe – we will get the teams working on it, and we would love to get a blood test screen for those conditions in addition to this cancer screen." (deSouza (Illumina) Tr. 2356.)

Response to Finding No. 1142.1

The proposed finding is misleading and incomplete, and it should be disregarded. When Mr. deSouza was asked on direct to "[g]ive us some examples . . . of the kinds of R&D efficiencies that the transaction will create independent of the Galleri test," Mr. deSouza responds, "We believe that . . . we will bring our R&D teams together and immediately start the

work [for non-MCED applications]. We believe – we will get the teams working on it, and we would love to get a blood test for those conditions in addition to this cancer screen." In other words, Mr. deSouza's testimony amounts to saying Illumina has smart employees. That does not make for a verifiable and merger-specific efficiency. Moreover, simply saying that the two companies' teams will "immediately start the work" and will "get . . . working on it" does not say anything about how this Acquisition will generate any cognizable R&D efficiency.

The proposed finding is irrelevant in that it suggests—without any concrete evidence—that the Acquisition will generate efficiencies outside of the relevant market. Respondents appear to make inappropriate attempts to justify their anticompetitive merger by asserting unsubstantiated efficiencies outside of the relevant market.

> 1142.2 Alex Aravanis, Chief Technology Officer at Illumina and former head of R&D at GRAIL testified that: "There's a couple ways that we think the transaction will lead to R&D benefits to the larger Illumina. One is novel discoveries. So our experience, for example, in noninvasive prenatal testing is that when you operate a clinical test as a large service, you will have additional findings. Those could give insights into other types of diseases that GRAIL's technology could be useful for. For example, fatty liver disease or neurodegenerative disease. Those are other applications Illumina would pursue. In addition, we've found that there's significant cross-pollination between applications, meaning that there's aspects of GRAIL's methylation technology that could be useful for noninvasive prenatal testing or genetic disease testing." (Aravanis (Illumina) Tr. 1954.)

Response to Finding No. 1142.2

The proposed finding is irrelevant in that it suggests—without any concrete evidence—that the Acquisition will generate efficiencies outside of the relevant market. Respondents appear to make inappropriate attempts to justify their anticompetitive merger by asserting unsubstantiated efficiencies outside of the relevant market. The proposed finding should therefore be disregarded.

> 1142.3 Phil Febbo, Chief Medical Officer at Illumina, testified that "I see this kind of platform as having significant impact certainly in cancer testing. We'll see screening, which is what we're talking about. We'll also see these kind of signals helpful

> in cancer monitoring, but outside of cancer, we know that these signals could pick up on metabolic disease. So in the United States, obesity is a major challenge. There's fatty acid – fatty changes in the liver, or NASH, causing NASH, an increasing healthcare concern, and I am confident – I don't know which application will go first, whether it's cardiovascular disease, metabolic disease, inflammatory disease – but I'm quite confident that as we look at these outliers, we'll see opportunities to build tests that serve as many, if not – as many patients as the screening test can serve." (Febbo Tr. 4359–60.)

Response to Finding No. 1142.3

The proposed finding is irrelevant in that it suggests—without any concrete evidence—that the Acquisition will generate efficiencies outside of the relevant market. Respondents appear to make inappropriate attempts to justify their anticompetitive merger by asserting unsubstantiated efficiencies outside of the relevant market. The proposed finding should therefore be disregarded.

> 1142.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "we could take advantage of the data that's coming from the international expansion, human blood carries markers for all kinds of diseases, some of those yet to be discovered, but we do know that there are markers in the blood for neurologic diseases, such as Alzheimer's, markers for conditions like diabetes, and because GRAIL, again, has to be so focused on the Galleri test, they don't have the ability to move rapidly to develop these other tests, where in combination with Illumina, we could delegate resources to work on these other tests and bring follow-on, complementary tests to the market much more quickly." (Flatley (Illumina) Tr. 4088–89.)

Response to Finding No. 1142.4

The proposed finding is irrelevant in that it suggests—without any concrete evidence—that the Acquisition will generate efficiencies outside of the relevant market. Respondents appear to make inappropriate attempts to justify their anticompetitive merger by asserting unsubstantiated efficiencies outside of the relevant market. The proposed finding should therefore be disregarded.

> 1142.5 Here, again, Complaint Counsel did not put on any fact witnesses that undermined or even attempted to contradict this testimony.

Response to Finding No. 1142.5

The proposed finding is unsupported because it does not cite to any evidence within the factual record. It should therefore be disregarded. The proposed finding is misleading and incomplete to the extent it incorrectly suggest Complaint Counsel did not elicit testimony and present documents to refute Respondents' baseless R&D claims, as explained in proposed findings that include cites to evidence in the record.

The proposed finding is irrelevant in that it suggests the Acquisition will generate efficiencies outside of the relevant market. Respondents appear to make inappropriate attempts to justify their anticompetitive merger by asserting unsubstantiated efficiencies outside of the relevant market.

1143. Respondents' experts corroborated the undisputed fact testimony that R&D efficiencies will arise from the reunion of Illumina and GRAIL.

Response to Finding No. 1143

The proposed finding is unsupported because it does not cite to any evidence within the factual record. It should therefore be disregarded.

> 1143.1 As Dr. Carlton has explained: "simply put, you put some scientists who know one thing with scientists who know another thing, you put them together, and out of that collaboration comes new products, new ideas, new ways of doing things that could not just lower costs but create — create new products. . . But my understanding is that the possibility for such types of R&D discoveries is a real one as a result of this transaction and that some of these possibilities include being able to do screening not just for cancer, but for neurodegenerative diseases, like Alzheimer's, fatty liver disease, cardiovascular disease. So all of these, it's my understanding, are possible benefits from this R&D collaboration". (RX6000 (Carlton Trial, Dep. at 61–62).)

Response to Finding No. 1143.1

The proposed finding is confusing and unsupported and should be disregarded. Respondents appear to argue that they will generate efficiencies simply by putting "some scientists who know one thing with scientists who know another thing" without specifying what "things" these scientists apparently know or why this merger is necessary to achieve these

efficiencies. Dr. Carlton testified that his "understanding is that the possibility for such types of R&D discoveries is a real one as a result of this transaction," but the proposed finding does not explain why.

Illumina does not—because it cannot—identify the specific breakthroughs, products, or benefits which may result, nor does Illumina identify the timing, likelihood, or cost to achieve such alleged benefits. Indeed, Illumina's corporate designee testifying about efficiencies conceded that "Illumina [had] not attempted to quantify these [claimed R&D efficiencies]," (CCFF ¶ 5735), as did Dr. Carlton, who testified that he did not quantify the benefit of R&D efficiency, (CCFF ¶ 5727), did not attempt to estimate the scale of R&D efficiencies, (CCFF ¶ 5728), and did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (CCFF ¶ 5730). Indeed, Dr. Carlton conceded in his deposition that "it's hard to make predictions as to exactly what R&D efficiencies would result," (CCFF ¶ 5729), and as such, he did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies, (CCFF ¶ 5731), or attempt to identify what specific products may result from the claimed R&D efficiencies. (CCFF ¶ 5732). As Complaint Counsel's efficiency expert correctly concluded,

[redacted]

1144. The evidence of R&D efficiencies is unrefuted.

Response to Finding No. 1144

The proposed finding is unsupported by any evidence and should be disregarded. Moreover, the proposed finding is incorrect. Complaint Counsel cross-examined Respondents' expert witness, Dr. Carlton, extensively about R&D efficiencies, Complaint Counsel's expert witnesses, Dr. Rothman and Dr. Scott Morton, opined on R&D efficiencies in their reports and trial testimony, and Complaint Counsel produced dozens of findings of fact refuting Respondents' R&D efficiencies evidence. (*see* CCFF ¶¶ 5721-5756).

1144.1 [redacted]

Response to Finding No. 1144.1

[redacted]

1144.2 Instead, Dr. Rothman states that the efficiency is not cognizable because Dr. Carlton did not assess the specific efficiencies that will be created or the cost of those efficiencies. (RX3854 (Rothman Dep. at 25–34).)

Response to Finding No. 1144.2

The proposed finding is incomplete and misleading insofar as it suggests that this was Dr. Rothman's only conclusion related to R&D efficiencies or that Dr. Rothman was the only person to dispute the testimony from Illumina and Grail witnesses related to R&D efficiencies.

[redacted] Moreover, other witnesses, including Dr. Scott Morton, testified about R&D efficiencies, and Complaint Counsel refuted Illumina and Grail witness testimony on this topic through cross-examination. Therefore, the proposed finding is misleading and incomplete, and it should be disregarded.

1144.3 However, Dr. Rothman fails altogether to account for the undisputed fact testimony illustrated above; he simply ignores it.

Response to Finding No. 1144.3

The proposed finding is unsupported and vague. It is vague because it does not define the "undisputed fact testimony illustrated above." Because all of Respondents' testimony (fact

and otherwise) was disputed by Complaint Counsel, it is unclear which evidence the proposed finding is referring to. It is also unsupported by any evidence and should therefore be disregarded.

> 1144.4 Dr. Rothman also does not explain why understanding the exact costs of these efficiencies is necessary in order for them to be cognizable.

Response to Finding No. 1144.4

The proposed finding is unsupported and vague. It is vague because it does not explain what "exact costs" or "these efficiencies" mean. The proposed finding is also confusing because it lacks context and is thus difficult to respond to without more information. It is also unsupported by any evidence and should therefore be disregarded.

> 1144.5 Moreover, Dr. Rothman admittedly only assessed the evidence in Dr. Carlton's report and did not assess any other evidence, including affirmative testimony offered by Respondents' witnesses at trial. (RX3854 (Rothman, Dep. at 74–78) ("A.. . My analysis is of the claims that – – certain claims that Dr. Carlton, Dr. Deverka and Mr. Serafin Make in their reports. . . . Q So if – you don't know whether there is additional evidence out there that supports any of those claimed efficiencies beyond what they cited, do you? . . . A. My analysis was of what they offered as substantiation for certain claimed efficiencies. . . . Q. GRAIL and Illumina's witnesses have not yet offered their direct testimony at trial, have they? We can agree on that? A. Yes. Q. Okay. You don't know what those witnesses are going to say under direct examination, by definition, right? A. That's correct".)).

Response to Finding No. 1144.5

The proposed finding is incorrect, misleading, and unsupported. It is incorrect because it claims that Dr. Rothman only assessed the evidence in Dr. Carlton's report, but in the quoted passage, Dr. Rothman confirms that he considered reports from Dr. Carlton, Dr. Deverka, and Mr. Serafin. (RX3854 (Rothman Dep. at 74)). It is misleading insofar as it suggests that Dr. Rothman did not review the factual record when writing his report. Dr. Rothman testified that he reviewed, among other things, certain investigational hearing transcripts and certain deposition transcripts. (RX3854 (Rothman Dep. at 77)). It is also misleading to suggest that Dr. Rothman

should have included in his report some of the trail testimony of the Illumina and Grail witnesses. Dr. Rothman's report was due on July 26, well in advance of trial and any affirmative testimony from Respondents. If he then took that testimony into account, he would be violating this Court's mandate not to go beyond the scope of his report. Finally, the contention in the proposed finding that Dr. Rothman did not assess any evidence beyond what was in Dr. Carlton's report is completely unfounded. Therefore, the finding should be disregarded.

> 1144.6 [redacted] However, the firewall in the Open Offer is designed to protect against the sharing of third party confidential information and does not prevent Illumina and GRAIL from engaging in R&D activities. (RX3340 (Illumina Open Offer at 7–8) ("Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise".).) Thus, it has no bearing on the R&D efficiencies shown at trial.

Response to Finding No. 1144.6

The proposed finding is unsupported and misleading. It is unsupported because it does not explain how the Open Offer "does not prevent Illumina and Grail from engaging in R&D activities." The citation in the proposed finding demonstrates only that there is a firewall between Illumina and Grail, as Dr. Scott Morton testified. There is no other support for Respondents' contention that "it has no bearing on the R&D efficiencies shown at trial." Therefore, the proposed finding should be disregarded. [redacted]

1145. Complaint Counsel also ignores Illumina's track record of generating R&D efficiencies in a vertical transaction.

Response to Finding No. 1145

The proposed finding is completely unsupported by evidence and should be disregarded. It is also vague because it does not specify what Illumina's track record is of generating R&D efficiencies in a vertical transaction or which vertical transaction (or transactions) Respondents may be referring to.

> 1145.1 Illumina's track record of generating R&D efficiencies in a vertical transaction substantiates the R&D efficiencies.

Response to Finding No. 1145.1

The proposed finding is completely unsupported by evidence and should be disregarded. It is also vague because it does not specify what Illumina's track record is of generating R&D efficiencies in a vertical transaction or which vertical transaction (or transactions) Respondents may be referring to. It also does not explain why this track record should substantiate any claimed R&D efficiencies in this case. In order to substantiate their claimed efficiencies here, Respondents must demonstrate that the claims are verifiable, merger-specific, and would be passed through to consumers. (*see* Complaint Counsel's Post-Trial Reply Brief. § 5.C.).

> 1145.2 The idea for Galleri came from another vertical transaction: Illumina's acquisition of Verinata, a company in the non-invasive prenatal testing business. (Aravanis (Illumina) Tr. 1868–69; PX7048 (Klausner (GRAIL) IHT at 49–54).)

Response to Finding No. 1145.2

The proposed finding is incorrect and should be disregarded. This erroneous claim is flatly contradicted by record evidence. First, multiple other individuals were already exploring the potential use of cfDNA for an MCED test well before Illumina's acquisition of Verinata in 2013. For example, Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that could provide early detection of colon cancer. (CCFF ¶ 357). In March 2009, Dr. Ahlquist told Exact's CEO, Kevin Conroy, of his vision for detecting

many or most cancers from a simple blood draw. (CCFF ¶ 358). Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (CCFF ¶ 358). Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier, (CCFF ¶ 359), and [redacted] At the same time Exact was working with Dr. Ahlquist on its MCED test, Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (CCFF ¶ 361). Dr. Vogelstein was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies," (CCFF ¶ 363), and he ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (CCFF ¶ 365). Ultimately, Dr. Vogelstein became a co-founder of Thrive, (CCFF ¶ 366), and his discoveries led to the creation of Thrive's CancerSEEK MCED test. (CCFF ¶ 364).

Second, Illumina's internal documents directly contradict its claims that the Verinata transaction was the source of the discovery leading to Galleri. Specifically, Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings of National Academy of Science journal in 2008 presenting research on the detection of fetus chromosome trisomy using cfDNA. (CCFF ¶ 354). Dr. Gao used the research from his 2008 paper with Dr. Dennis Lo to begin research on the use of cfDNA for cancer screening. (CCFF ¶ 354). As early as 2009, Dr. Gao published a paper on DNA methylation for use in applications such as cancer detection in 2009 with Singlera co-founder Professor Kun Zhang of the University of California San Diego.

(CCFF ¶ 355). By 2012, Dr. Lo's research caught the attention of Illumina. In August 2012, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina's SVP of Corporate and Venture Development, Nicholas Naclerio, to alert Naclerio of research by Dr. Dennis Lo. (CCFF ¶ 369). Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [noninvasive prenatal testing]," (CCFF ¶ 371), and suggested that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (CCFF ¶ 372). Just one month later, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought to review Dr. Lo's "filed patent applications." (CCFF ¶ 373). In notes from the call, Illumina's attendees wrote the question, "How will a clinician use this type of data?" (CCFF ¶ 373). Responses to the question included "*Blood biopsy – non-invasive screening" and "Potential for detecting cancer prior to actual detection of a primary tumor*." (CCFF ¶ 363 (emphasis added)).

> 1145.3 In the first hundred thousand women that received Illumina's noninvasive prenatal test, some unusual signals were identified. (Aravanis (Illumina) Tr. 1868–69; PX7048 (Klausner (GRAIL) IHT at 49–54).)

Response to Finding No. 1145.3

The proposed finding is vague and misleading and should be disregarded. It is vague because it lacks context and does not define the term "unusual signals." It is also misleading to the extent that it suggests that Illumina's acquisition of Verinata was the source of discovery leading to Galleri. This erroneous claim is flatly contradicted by record evidence. First, multiple other individuals were already exploring the potential use of cfDNA for an MCED test well before Illumina's acquisition of Verinata in 2013. For example, Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that could provide early detection of colon cancer. (CCFF ¶ 357). In March 2009, Dr. Ahlquist told

Exact's CEO, Kevin Conroy, of his vision for detecting many or most cancers from a simple blood draw. (CCFF ¶ 358). Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (CCFF ¶ 358). Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier, (CCFF ¶ 359), [redacted] At the same time Exact was working with Dr. Ahlquist on its MCED test, Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (CCFF ¶ 361). Dr. Vogelstein was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies," (CCFF ¶ 363), and he ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (CCFF ¶ 365). Ultimately, Dr. Vogelstein became a co-founder of Thrive, (CCFF ¶ 366), and his discoveries led to the creation of Thrive's CancerSEEK MCED test. (CCFF ¶ 364).

Second, Illumina's internal documents directly contradict its claims that the Verinata transaction was the source of the discovery leading to Galleri. Specifically, Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings of National Academy of Science journal in 2008 presenting research on the detection of fetus chromosome trisomy using cfDNA. (CCFF ¶ 354). Dr. Gao used the research from his 2008 paper with Dr. Dennis Lo to begin research on the use of cfDNA for cancer screening. (CCFF ¶ 354). As early as 2009, Dr. Gao published a paper on DNA methylation for use in applications such as cancer detection in 2009 with Singlera co-founder Professor Kun Zhang of the University of California San Diego.

(CCFF ¶ 355). By 2012, Dr. Lo's research caught the attention of Illumina. In August 2012, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina's SVP of Corporate and Venture Development, Nicholas Naclerio, to alert Naclerio of research by Dr. Dennis Lo. (CCFF ¶ 369). Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [noninvasive prenatal testing]," (CCFF ¶ 371), and suggested that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (CCFF ¶ 372). Just one month later, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought to review Dr. Lo's "filed patent applications." (CCFF ¶ 373). In notes from the call, Illumina's attendees wrote the question, "How will a clinician use this type of data?" (CCFF ¶ 373). Responses to the question included "*Blood biopsy – non-invasive screening" and "Potential for detecting cancer prior to actual detection of a primary tumor*." (CCFF ¶ 363 (emphasis added)).

> 1145.4 Illumina formed a team and a program to evaluate early cancer detection signals and to follow up with patients and their prescribing physicians, which led to the discovery that the women with the unusual NIPT results had undiagnosed cancers. (Aravanis (Illumina) Tr. 1869–70; PX7048, (Klausner (GRAIL) IHT at 49–54).)

Response to Finding No. 1145.4

The proposed finding is vague and misleading and should be disregarded. It is vague because it lacks context and does not define the term "unusual NIPT results." It is also misleading to the extent that it suggests that Illumina's acquisition of Verinata was the source of discovery leading to Galleri. This erroneous claim is flatly contradicted by record evidence. First, multiple other individuals were already exploring the potential use of cfDNA for an MCED test well before Illumina's acquisition of Verinata in 2013. For example, Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that

could provide early detection of colon cancer. (CCFF ¶ 357). In March 2009, Dr. Ahlquist told Exact's CEO, Kevin Conroy, of his vision for detecting many or most cancers from a simple blood draw. (CCFF ¶ 358). Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (CCFF ¶ 358). Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier, (CCFF ¶ 359), [redacted] At the same time Exact was working with Dr. Ahlquist on its MCED test, Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (CCFF ¶ 361). Dr. Vogelstein was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies," (CCFF ¶ 363), and he ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (CCFF ¶ 365). Ultimately, Dr. Vogelstein became a co-founder of Thrive, (CCFF ¶ 366), and his discoveries led to the creation of Thrive's CancerSEEK MCED test. (CCFF ¶ 364).

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with Singlera co-founder Professor Kun Zhang of the University of California San Diego. (CCFF ¶ 355). By 2012, Dr. Lo's research caught the attention of Illumina. In August 2012, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina's SVP of Corporate and Venture Development, Nicholas Naclerio, to alert Naclerio of research by Dr. Dennis Lo. (CCFF ¶ 369). Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [noninvasive prenatal testing]," (CCFF ¶ 371), and suggested that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (CCFF ¶ 372). Just one month later, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought to review Dr. Lo's "filed patent applications." (CCFF ¶ 373). In notes from the call, Illumina's attendees wrote the question, "How will a clinician use this type of data?" (CCFF ¶ 373). Responses to the question included "*Blood biopsy – non-invasive screening" and "Potential for detecting cancer prior to actual detection of a primary tumor*." (CCFF ¶ 363 (emphasis added)).

> 1145.5 It is that discovery that ultimately led Illumina to pursue development of an early cancer detection test and to found GRAIL. (Aravanis (Illumina) Tr. 1871; PX7048 (Klausner (GRAIL) IHT at 43–44, 69–72).)

Response to Finding No. 1145.5

The proposed finding is vague and misleading and should be disregarded. It is vague because it lacks context and does not define the term "that discovery." It is also misleading to the extent that it suggests that Illumina's acquisition of Verinata was the source of discovery leading to Galleri. This erroneous claim is flatly contradicted by record evidence. First, multiple other individuals were already exploring the potential use of cfDNA for an MCED test well before Illumina's acquisition of Verinata in 2013. For example, Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that

could provide early detection of colon cancer. (CCFF ¶ 357). In March 2009, Dr. Ahlquist told Exact's CEO, Kevin Conroy, of his vision for detecting many or most cancers from a simple blood draw. (CCFF ¶ 358). Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (CCFF ¶ 358). Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier, (CCFF ¶ 359), [redacted] At the same time Exact was working with Dr. Ahlquist on its MCED test, Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (CCFF ¶ 361). Dr. Vogelstein was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies," (CCFF ¶ 363), and he ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (CCFF ¶ 365). Ultimately, Dr. Vogelstein became a co-founder of Thrive, (CCFF ¶ 366), and his discoveries led to the creation of Thrive's CancerSEEK MCED test. (CCFF ¶ 364).

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> 1145.6 As Jay Flatley testified: "If you go back to the origin of GRAIL, one of the most important things that happened there was our acquisition of Verinata because it was that work that really was the light bulb moment that I think I described to you last time, about the actual failures in a number of cases of the NIPT test that caused us to realize that you can detect cancer by screening the blood. So those kinds of magical moments happen when you put people together that are working in related areas. So certainly some great opportunities would evolve there". (PX7079 **(**Flatley (Illumina) Dep. at 31–32).) This project was enabled by Illumina's acquisition of Verinata.

Response to Finding No. 1145.6

The proposed finding is vague and misleading and should be disregarded. It is vague because it lacks context and does not define the terms "that work," "great opportunities would evolve there," or "this project." It also does not explain why this Court should credit any claimed R&D efficiencies in this case. In order to substantiate their claimed efficiencies,

Respondents must demonstrate that the claims are verifiable, merger-specific, and would be passed through to consumers. (*see* Complaint Counsel's Post-Trial Repl. Brief § 5.C.).

Moreover, it is also misleading to the extent that it suggests that Illumina's acquisition of Verinata was the source of discovery leading to Galleri. This erroneous claim is flatly contradicted by record evidence. First, multiple other individuals were already exploring the potential use of cfDNA for an MCED test well before Illumina's acquisition of Verinata in 2013. For example, Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that could provide early detection of colon cancer. (CCFF ¶ 357). In March 2009, Dr. Ahlquist told Exact's CEO, Kevin Conroy, of his vision for detecting many or most cancers from a simple blood draw. (CCFF ¶ 358). Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (CCFF ¶ 358). Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier, (CCFF ¶ 359), [redacted] At the same time Exact was working with Dr. Ahlquist on its MCED test, Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (CCFF ¶ 361). Dr. Vogelstein was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies," (CCFF ¶ 363), and he ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (CCFF ¶ 365). Ultimately, Dr. Vogelstein became a co-founder of Thrive, (CCFF ¶ 366), and his discoveries led to the creation of Thrive's CancerSEEK MCED test. (CCFF ¶ 364).

Second, Illumina's internal documents directly contradict its claims that the Verinata transaction was the source of the discovery leading to Galleri. Specifically, Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings of National Academy of Science journal in 2008 presenting research on the detection of fetus chromosome trisomy using cfDNA. (CCFF ¶ 354). Dr. Gao used the research from his 2008 paper with Dr. Dennis Lo to begin research on the use of cfDNA for cancer screening. (CCFF ¶ 354). As early as 2009, Dr. Gao published a paper on DNA methylation for use in applications such as cancer detection in 2009 with Singlera co-founder Professor Kun Zhang of the University of California San Diego. (CCFF ¶ 355). By 2012, Dr. Lo's research caught the attention of Illumina. In August 2012, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina's SVP of Corporate and Venture Development, Nicholas Naclerio, to alert Naclerio of research by Dr. Dennis Lo. (CCFF ¶ 369). Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [noninvasive prenatal testing]," (CCFF ¶ 371), and suggested that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (CCFF ¶ 372). Just one month later, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought to review Dr. Lo's "filed patent applications." (CCFF ¶ 373). In notes from the call, Illumina's attendees wrote the question, "How will a clinician use this type of data?" (CCFF ¶ 373). Responses to the question included "*Blood biopsy – non-invasive screening" and "Potential for detecting cancer prior to actual detection of a primary tumor*." (CCFF ¶ 363 (emphasis added)).

1145.7 Similarly, Rick Klausner, one of the founders of GRAIL, testified that: "So very soon after I had started at Illumina, I received either an e-mail or a phone call

> from a pathologist named Meredith Miller, who had been working at a company called Verinata that Illumina had at that time I think relatively recently acquired. And this was a company that was performing an LDT called NIPT for noninvasive prenatal testing, which is basically a liquid biopsy company I guess of sorts, but it's . . . not a company. It's a technology that measures the same type of circulating fragments of DNA that we now have been looking at for early cancer detection. And she had known of me. I think I had met her in the past. But told me a story that . . . she was the pathologist who was reading and signing off on the NIPT results and told me that she had collected a small number, less than 15 . . . of, as she described them, really weird results. And she didn't understand the results. She told me that she had basically concluded that the test didn't work, but to her great, you know, I think it's terrific that she was puzzled by and kept them. She wondered what they were. This was all happening very quickly because the scaleup of very long NIPT by multiple companies, including Verinata and then Illumina, had just gone very rapidly, hundreds of thousands of these tests, you know, quite extraordinary, and that was important, because of the hundred to thousand I don't remember the precise number that they had run, she only had these 12 to 15 that were, quote, this similar weird pattern. And she asked me if she could bring them by to show me these genomic readouts to see if I had any ideas about what was going on. So that was the framing of what was then going to change my mind about the possibility of a multicancer detection test." (PX7048 (Klausner (GRAIL) IHT at 43-44).)

Response to Finding No. 1145.7

The proposed finding is vague and misleading and should be disregarded. It is vague because it lacks context, and it also does not explain why this Court should credit any claimed R&D efficiencies in this case. [redacted]

Moreover, it is also misleading to the extent that it suggests that Illumina's acquisition of Verinata was the source of discovery leading to Galleri. This erroneous claim is flatly contradicted by record evidence. [redacted]

[redacted]

Second, Illumina's internal documents directly contradict its claims that the Verinata transaction was the source of the discovery leading to Galleri. [redacted]

[redacted]

1145.8 Verinata did not have the resources to research and develop an early cancer detection test on its own, and but for Illumina acquiring Verinata no one would have developed an early cancer test research and development program despite the potential benefits of such a test. (Aravanis (Illumina) Tr. 1873–74.)

Response to Finding No. 1145.8

The proposed finding is unreliable, incorrect, and contradicted by other evidence in the record, and it should be disregarded. It is unreliable because it is supported only by the self-serving testimony of Dr. Aravanis, an Illumina executive, who benefits financially from the close of the acquisition.

Moreover, it is also misleading to the extent that it suggests that only Illumina could have brought about the discovery of MCED tests. This erroneous claim is flatly contradicted by record evidence. [redacted]

[redacted]

[redacted]

1145.9 Illumina's track record of generating R&D efficiencies in connection with a vertical transaction corroborates the R&D efficiencies proven here. (deSouza (Illumina) Tr. 2345 ("we believe that there are R&D synergies between the two teams, so just like our team discovered the possibility to see cancer in blood because we were processing NIPT samples, we believe that it is going to be possible to develop a diagnostic test, a blood diagnostic test, to look for fatty liver disease, Alzheimer's, Parkinson's. But that requires the capabilities of the two companies to be brought together, and so we believe there are R&D synergies there".); PX7079 (Flatley (Illumina) Dep. at 31–32) ("If you go back to the origin of GRAIL, one of the most important things that happened there was our acquisition of Verinata because it was that work that really was the light bulb moment . . . that caused us to realize that you can detect cancer by screening the blood. . . . So certainly some great opportunities would evolve there".).)

Response to Finding No. 1145.9

The proposed finding is vague, unreliable, and misleading and should be disregarded. It is vague because it lacks context and does not describe Illumina's "track record of generating R&D efficiencies" other than to repeat false claims about using Verinata to "discover" MCED tests. It is unreliable because it relies on support from self-serving testimony of two Illumina executives, Mr. deSouza and Dr. Aravanis, who benefit financially from the closure of the acquisition. Further, the proposed finding does not explain why this Court should credit any claimed R&D efficiencies in this case. [redacted]

Moreover, it is also misleading to the extent that it suggests that Illumina's acquisition of Verinata was the source of discovery leading to Galleri. This erroneous claim is flatly contradicted by record evidence. [redacted]

[redacted]

Second, Illumina's internal documents directly contradict its claims that the Verinata transaction was the source of the discovery leading to Galleri. [redacted]

[redacted]

D. The Reunion of Illumina and GRAIL Has Already Reduced GRAIL's Royalty Burden.

1146. The Transaction will lead to significant efficiencies by reducing royalties that GRAIL was required to pay Illumina before the Transaction.

Response to Finding No. 1146

The proposed finding is completely unsupported by evidence and should be disregarded. It is also misleading to the extent that it suggests that elimination of Grail's royalty payment to Illumina will result in verifiable and merger-specific efficiencies that will be passed through to customers. It will not. [redacted]

1146.1 [redacted] PX7073 (Aravanis (Illumina) IHT at 27).)

Response to Finding No. 1146.1

[redacted]

[redacted]

1146.2 [redacted]

Response to Finding No. 1146.2

[redacted]

1147. [redacted]

Response to Finding No. 1147

[redacted]

[redacted]

1147.1 [redacted]

Response to Finding No. 1147.1

[redacted]

1147.2 [redacted]

Response to Finding No. 1147.2

[redacted]

1147.3 [redacted]

Response to Finding No. 1147.3

[redacted]

[redacted]

1148. [redacted]

Response to Finding No. 1148

[redacted]

[redacted]

1148.1 [redacted]

Response to Finding No. 1148.1

[redacted]

[redacted]

1148.2 [redacted]

Response to Finding No. 1148.2

[redacted]

[redacted]

1148.3 [redacted]

Response to Finding No. 1148.3

[redacted]

[redacted]

1148.4 [redacted]

Response to Finding No. 1148.4

[redacted]

[redacted]

1148.5 [redacted]

Response to Finding No. 1148.5

[redacted]

[redacted]

1149. Royalty savings will be passed on to consumers.

Response to Finding No. 1149

The proposed finding is completely unsupported by evidence and should be disregarded. Respondents fail to even specify how much of the royalty will supposedly be passed through to consumers, offering contradictory statements in their own brief about the amount of this alleged efficiency. [redacted] The reason is that Respondents cannot calculate the amount of royalty that will be passed through, as their expert conceded that, [redacted]

1149.1 The reduction of royalties resulting from the Transaction will be passed on to consumers in the form of lower prices. (Freidin (GRAIL) Tr. 2975–77; [redacted].)

Response to Finding No. 1149.1

The proposed finding is unsupported and should be disregarded. Respondents fail to

even specify how much of the royalty will supposedly be passed through to consumers, offering contradictory statements in their own brief about the amount of this alleged efficiency. [redacted]

[redacted] The reason is that Respondents cannot calculate the amount of royalty that will be passed through, as their expert conceded that, [redacted]

1149.2 [redacted] (Freidin (GRAIL) Tr. 2975–77; [redacted].)

Response to Finding No. 1149.2

[redacted]

[redacted]

1149.3 [redacted] PX7073 (Aravanis (Illumina) IHT at 27).)

Response to Finding No. 1149.3

[redacted]

[redacted]

1149.4 Dr. Aravanis testified that "[i]t is Illumina's plan to pass 100% of those efficiency savings on to payers of the test, so, you know, physicians – or sorry – patients and, you know, other payers of the test". (PX7065 (Aravanis (Illumina) IHT at 27).)

Response to Finding No. 1149.4

The proposed finding is vague, unsupported, and unreliable. It is unreliable because it is based solely on the investigational hearing testimony of Dr. Aravanis, an Illumina executive who benefits financially from this Transaction. It is vague because it is unclear who Dr. Aravanis is referring to when he says "payers of the test." It is also unsupported because Dr. Aravanis provides no details or additional evidence for the amount of the alleged royalty efficiency that will be passed through to consumers. Therefore, this proposed finding should be disregarded.

Moreover, Respondents offer contradictory statements in their own brief about the amount of this alleged efficiency. [redacted] The reason is that Respondents cannot calculate the

amount of royalty that will be passed through, as their expert conceded that, [redacted]

[redacted]

1149.5 [redacted]

Response to Finding No. 1149.5

[redacted]

[redacted]

1150. [redacted]

Table 13

[redacted]

[redacted]

Response to Finding No. 1150

[redacted]

[redacted]

[redacted]

1150.1 [redacted]

Response to Finding No. 1150.1

[redacted]

[redacted]

1151. The royalty efficiency is unrefuted.

Response to Finding No. 1151

The proposed finding is completely unsupported by evidence and should be disregarded.

[redacted]

[redacted]

1151.1 Complaint Counsel does not offer any fact witness testimony to the effect that the Transaction did not reduce GRAIL's royalty obligation.

Response to Finding No. 1151.1

The proposed finding is completely unsupported by evidence and should be disregarded. [redacted] The proposed finding is also misleading. Aside from being incorrect factually given the extensive cross examinations conducted in this case, it also misapplies the legal standard. It is not Complaint Counsel's burden to prove a negative – i.e., that no efficiencies occurred or that Respondents vague proclamations are inaccurate – but rather Respondents' burden to provide verifiable evidence to meet their burden. (*see Otto Bock*, 2019 WL 2118886 at *50). [redacted]

1151.2 Moreover, Complaint Counsel's experts do not opine on this efficiency in their reports.

Response to Finding No. 1151.2

The proposed finding is completely unsupported by evidence and should be disregarded. It is also incorrect. [redacted]

[redacted] The proposed finding is also misleading. Aside from being incorrect factually given the extensive cross examinations conducted in this case, it also misapplies the legal standard. It is not Complaint Counsel's burden to prove a negative – i.e., that no efficiencies occurred or that Respondents vague proclamations are inaccurate – but rather Respondents' burden to provide verifiable evidence to meet their burden. (*see Otto Bock*, 2019 WL 2118886 at *50). [redacted]

1151.3 [redacted]

Response to Finding No. 1151.3

[redacted]

1151.4 [redacted]

Response to Finding No. 1151.4

[redacted]

[redacted]

1151.5 [redacted] (Aravanis (Illumina) Tr. 1959–61; deSouza (Illumina) Tr. 2358–70; Freidin (GRAIL) Tr. 2977; PX7065 (Aravanis (Illumina) IHT at 55–56)) and [redacted]

Response to Finding No. 1151.5

[redacted]

E. Illumina and GRAIL Reunification Will Result in the Elimination of Double Marginalization

1152. Elimination of Double Marginalization or EDM is a well-documented efficiency from a vertical transaction that occurs when an upstream firm acquires a downstream firm to which it supplies inputs. (PFF ¶¶ 1152.1–1152.2.)

Response to Finding No. 1152

[redacted]

[redacted]

1152.1 [redacted]

Response to Finding No. 1152.1

[redacted]

[redacted]

1152.2 As explained by Dr. Carlton: "EDM benefits arise when an upstream firm with market power acquires a downstream firm with market power to which it supplies inputs. As separate entities, each firm maximizes its profits by setting its price such that the marginal revenue from an additional sale equals the marginal cost of an additional sale. When the upstream and downstream firms operate in markets that are not perfectly competitive, each firm sets its optimal price at a markup over marginal cost. . . . When the upstream and downstream firms merge, there is a single firm with the marginal costs of what was formerly the upstream firm and which faces the same demand curve as the former downstream firm. Thus, the margin of the upstream firm is internalized and there is an effective reduction in the marginal cost of producing the downstream product; put differently, the merger leads a profit maximizing firm to eliminate the upstream margin from its downstream pricing decision and to reduce the price of the downstream good". (RX3864 (Carlton Expert Report) ¶ 102–.)

Response to Finding No. 1152.2

The proposed finding is misleading and incomplete, and it should be disregarded. The

proposed finding omits that Dr. Carlton, has also explained in this textbook that [redacted]. Based on this evidence, [redacted]

1153. The conditions for elimination of double marginalization are present in this Transaction.

Response to Finding No. 1153

The proposed finding is incorrect and completely unsupported by evidence. It should therefore be disregarded. [redacted]

[redacted]

1153.1 Before the Transaction closed, Illumina charged a margin to GRAIL on sales of its NGS products, and GRAIL projected a margin on its products. (deSouza (Illumina) Tr. 2359–60; Aravanis (Illumina) Tr. 1960.)

Response to Finding No. 1153.1

The proposed finding is misleading and incomplete, and it should be disregarded. [redacted]

Further, the testimony of Mr. deSouza related to EDM is unreliable. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 (deSouza) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza) IHT at 259). Mr. deSouza also lacks the foundation to testify about the elimination of double marginalization. [redacted]

[redacted] Accordingly, Mr. deSouza's made-for-litigation testimony should be disregarded given that he is biased and lacks foundation. [redacted]

> 1153.2 As Dr. Carlton testified "[i]f you look at the data, if you look, for example, at the deal model, what is Illumina projecting is going to be happening, say, in – you know, in the future, there's double-marginalization, period. That's what the evidence is. What about now? Yes. There is just no question, double-marginalization is going on now, double-marginalization in the sense that price that is being charged to GRAIL is not marginal cost. That's just crystal clear in the data. So they haven't gotten rid of double-marginalization. As far as I can tell, Illumina has never gotten rid of double-marginalization with GRAIL or any of these third-party MCED developers. There's always a margin. But just look at the deal model. That is really excellent evidence. The deal model is telling you, absent the merger, here are Illumina's projections. No question, crystal clear, there is a margin that Illumina is charging to GRAIL". (RX6000 (Carlton Trial Dep. at 66–67).)

Response to Finding No. 1153.2

The proposed finding is misleading and incomplete. Even if Illumina and Grail both have margins pre-merger, it does not mean that they will be incentivized to lower Grail's prices post-merger. Dr. Carlton has explained in this textbook that [redacted] Based on this evidence, [redacted]

[redacted]

1154. [redacted]

Table 14

[redacted]

[redacted]

Response to Finding No. 1154

[redacted]

[redacted]

Further, the testimony of Mr. deSouza related to EDM is unreliable. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 (deSouza) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza) IHT at 259). Mr. deSouza also lacks the foundation to testify about the elimination of double marginalization. [redacted]

1155. The EDM efficiency is unrefuted.

Response to Finding No. 1155

The proposed finding is incorrect and completely unsupported by evidence. It should therefore be disregarded. Complaint Counsel, through cross examination of Respondents' witnesses and testimony from Dr. Fiona Scott Morton, have thoroughly refuted Respondents'

EDM efficiency argument. [redacted] As stated elsewhere in the reply findings, [redacted]

1155.1 Complaint Counsel does not present any factual testimony or other evidence suggesting that there were not two margins prior to the Transaction or that the elimination of double marginalization will not be achieved.

Response to Finding No. 1155.1

The proposed finding is incorrect and completely unsupported by evidence. It should therefore be disregarded. Complaint Counsel, through cross examination of Respondents' witnesses and testimony from Dr. Fiona Scott Morton, have thoroughly refuted Respondents' EDM efficiency argument, [redacted] As stated elsewhere in the reply findings, [redacted]

1155.2 Rather, Complaint Counsel's economic expert argues that EDM will not be achieved here because Respondents could have achieved these procompetitive benefits before the Transaction, given the complex contracts that already existed between the parties, and chose not to do so. (RX3852 (Scott Morton Dep. at 224).)

Response to Finding No. 1155.2

The proposed finding is incomplete and misleading, and it should be disregarded. The proposed finding does not accurately capture Complaint Counsel's (or Dr. Scott Morton's) arguments related to EDM. For example, it omits that Dr. Carlton conceded that he [redacted] explained that his EDM calculations [redacted]

Moreover, even if Illumina and Grail both have margins pre-merger, it does not mean that they will be incentivized to lower Grail's prices post-merger. Dr. Carlton has explained in this textbook that [redacted]

[redacted]

1155.3 This assertion, however, follows from Dr. Scott Morton's unsupported assumption that EDM can easily be eliminated by contract, and hence, if double marginalization is not eliminated by contract, then the current pricing structure that exists must be efficient and would not be improved upon post-merger. (RX3852 (Scott Morton Dep. at 215–18).)

Response to Finding No. 1155.3

The proposed finding is incorrect, unsupported, and should be disregarded. The proposed finding does not provide any evidence for why Dr. Scott Morton's argument against Respondents' EDM efficiency is "unsupported." Respondents need only look to their own economic expert, Dr. Carlton, for support. Dr. Carlton has explained in this textbook that [redacted]

[redacted]

Moreover, the proposed finding omits that Dr. Carlton conceded that he [redacted] explained that his EDM calculations [redacted]

> 1155.4 But this reasoning, if true, would eliminate the rationale for every vertical merger, as all EDM benefits (as well as any other efficiencies) could be achieved by contract under Dr. Scott Morton's theory. In fact, Dr. Scott Morton's assumption flies in the face of longstanding economic literature, case law, and the Vertical Merger Guidelines. *See e.g., United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 193 (D.C. Cir 2018) ("EDM effect is 'generally accepted as a potential procompetitive benefit resulting from vertical mergers'") (quoting the DOJ's proposed findings of fact.)

Response to Finding No. 1155.4

The proposed finding is incorrect, unsupported, and should be disregarded. Respondents' cited materials merely suggest that EDM *may* result from *some* mergers—a proposition that Dr. Scott Morton does not deny. [redacted]. Respondents' have no answer to Dr. Scott Morton's analysis that, *in this specific merger*, EDM is unlikely to result because the Illumina and Grail were already engaged in [redacted] prior to the merger. Indeed, her conclusion is consistent with observations of Respondents' own economic expert, who has explained in this textbook that [redacted]

[redacted], [redacted]

[redacted] Ultimately, it is Respondents' burden to establish the likelihood and magnitude and the EDM efficiency, *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.), and Respondents have failed to demonstrate either in the face of record evidence suggesting that the merger is unlikely to result in any EDM effect.

> 1155.5 Even if EDM could be eliminated by contract in certain circumstances, the undisputed evidence shows that it was not and would not have been eliminated here. (deSouza (Illumina) Tr. 2359–60 (noting that Illumina and GRAIL each charged a margin prior to the transaction); Aravanis (Illumina) Tr. 1960 (same); *see also* RX6000 (Carlton Trial Dep. at 67–68) ("Well, you can say anything can happen. The fact of the matter is it hasn't happened. The reason why the evidence in this case is so strong, I think, to refute what Dr. Scott Morton is saying, is because it's obvious that, absent the merger, Illumina will charge GRAIL and does charge GRAIL and expects to charge GRAIL a price above its marginal cost, period. It's crystal clear from the documents".).)

Response to Finding No. 1155.5

The proposed finding is incorrect, unsupported, and should be disregarded. Respondents' cited materials merely suggest that EDM *may* result from *some* mergers—a proposition that Dr. Scott Morton does not deny. [redacted]. Respondents' have no answer to Dr. Scott Morton's analysis that, *in this specific merger*, EDM is unlikely to result because the Illumina and Grail were already engaged in [redacted] prior to the merger. Indeed, her conclusion is consistent with observations of Respondents' own economic expert, who has explained in this textbook that [redacted], [redacted]

[redacted] Ultimately, it is Respondents' burden to establish the likelihood and magnitude and the EDM

efficiency, *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.), and Respondents have failed to demonstrate either in the face of record evidence suggesting that the merger is unlikely to result in any EDM effect.

Further, the testimony of Mr. deSouza related to EDM is unreliable. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 (deSouza) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza) IHT at 259). Mr. deSouza also lacks the foundation to testify about the elimination of double marginalization. [redacted]

F. Reuniting Illumina and GRAIL Will to Lead to Supply, Operational and International Expansion

1156. The Transaction will not just save lives, accelerate market access, generate R&D efficiencies, reduce GRAIL's royalty burden and eliminate double marginalization. The reunion of Illumina and GRAIL will also (1) lead to supply chain and operational efficiencies and (2) accelerate the international expansion of Galleri.

Response to Finding No. 1156

The proposed finding is entirely unsupported and should be disregarded on this basis. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1. **The Reunion of Illumina and GRAIL Will Lead to Supply Chain and Operational Efficiencies.**

1157. Reuniting Illumina and GRAIL will allow them to achieve significant supply chain and operational efficiencies. (deSouza (Illumina) Tr. 2371–72; Aravanis (Illumina) Tr. 1961; Flatley (Illumina) Tr. 4086; Bishop (GRAIL) Tr. 1405.)

Response to Finding No. 1157

The proposed finding is inherently speculative, unsupported, and against the weight of the evidence. Respondents' proposed finding relies only on vague and speculative claims made by their own executives that are unsupported by ordinary course documents and do not meet the requisite threshold to show that the claimed efficiencies are cognizable. Respondents did not include efficiencies related to supply chain and laboratory operations in their Answer. [redacted] Further, in [redacted]

Respondents also failed to demonstrate that the supply chain and operational efficiencies are merger specific. [redacted] Further, the record evidence shows that these efficiencies are not merger specific because they could be achieved by Grail on its own. For example, at the time of the Transaction, [redacted] As a result of these initiatives, Grail projected [redacted]

[redacted]

Therefore, Respondents supply chain and operational efficiencies are not cognizable because they have failed to demonstrate that the cost savings could not be achieved by Grail alone. [redacted] Therefore, this Court should disregard the proposed finding.

1158. The evidence of this is entirely one-sided, fully favoring Respondents. Complaint Counsel presented no fact witness or other evidence rebutting the testimony of Respondents' fact witnesses on these efficiencies.

Response to Finding No. 1158

The proposed finding is wholly unsupported, incorrect, and against the weight of the substantial evidence demonstrating that [redacted] Therefore, this Court should disregard the proposed finding.

1159. Illumina has been operating in the NGS space for over a decade. During that time, Illumina has developed relationships with suppliers from whom it purchases in large

volumes. (Flatley (Illumina) Tr. 4085 ("That supply chain is very deep. It goes all the way back to primary formulations of products".).)

Response to Finding No. 1159

Complaint Counsel does not disagree that Illumina has been operating in the NGS space for over a decade. [redacted]

1160. These relationships allow Illumina to purchase inputs at a significant discount. (Aravanis (Illumina) Tr. 1960–61.); PX7073 (Aravanis (Illumina) 2.7(h) IHT) at 49–50.)

Response to Finding No. 1160

The proposed finding is misleading and against the weight of substantial evidence to the extent [redacted] Dr. Aravanis makes generalized, vague claims in his testimony regarding the "cost reductions associated with volume that Illumina benefits from could be shared with GRAIL as part of an integrated company," but never testified with any specificity or the magnitude of such savings. (Aravanis (Illumina) Tr. 1960-61). [redacted]. [redacted]. Therefore, this Court should disregard the proposed finding.

1161. By contrast, GRAIL is a young company that has only one product on the market with very limited sales. (Bishop (GRAIL) Tr. 1362–75, 1420.)

Response to Finding No. 1161

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that that Mr. Bishop's testimony supports the notion that alleged supply chain and operational efficiencies are merger specific. Respondents' expert, Dr. Carlton, did not perform an analysis to determine whether the supply chain and operational efficiencies claimed by Illumina are merger specific. (CCFF ¶ 5800). Further, the record evidence shows that these efficiencies are not merger specific because they could be achieved by Grail on its own. For example, at the time of the Transaction, [redacted] As Grail's CEO testified at trial, Grail built the RTP laboratory both to "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very

heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (CCFF ¶ 5808). As a result of these initiatives, Grail projected

[redacted]

Respondents' supply chain and operational efficiencies are not cognizable because they have failed to demonstrate that the cost savings could not be achieved by Grail alone and have not accounted for any costs associated with achieving them. (CCFF ¶¶ 5798, 5799). In short, the proposed finding is contradicted by the weight of substantial record evidence demonstrating that the claimed operational and supply chain efficiencies are not verifiable (CCFF ¶¶ 5786-5799) and not merger-specific (CCFF ¶¶ 5800-5836). Therefore, this Court should disregard the proposed finding.

1162. It is well recognized that purchasing in large volume can generate cost saving to the supplier and that can lead to volume discounts. The reunion of Illumina and GRAIL will allow GRAIL to benefit from Illumina's prices and relationships in areas of common products.

Response to Finding No. 1162

Complaint Counsel has no specific response to the first sentence. Complaint Counsel objects to the second sentence of the proposed finding as it is wholly unsupported and contradicted by the weight of substantial evidence demonstrating that the claimed efficiencies are neither verifiable (or quantifiable) nor merger-specific. *See, e.g.*, Response to RPFF ¶ 1157; *see also* (CCFF ¶¶ 5786-5836). Therefore, this Court should disregard the second sentence of the

proposed finding.

1162.1 Multiple witnesses addressed these efficiencies:

Response to Finding No. 1162.1

The proposed finding is misleading, wholly unsupported and contradicted by the weight of substantial evidence demonstrating that the claimed efficiencies are neither verifiable (or quantifiable) nor merger-specific. *See* Responses to RPFF ¶¶ 1162.2-1162.7; *see also* Response to RPFF ¶ 1157 and (CCFF ¶¶ 5786-5836). Therefore, this Court should disregard the proposed finding.

> 1162.2 Francis deSouza, CEO and President of Illumina, testified that: "We have supply contracts with a large number of suppliers, and we purchase a number of raw materials in – that GRAIL also uses in much higher quantities than GRAIL does. So what that means is we are able to get deeper discounts for those raw materials than GRAIL is able to do. And so by consolidating purchasing for these materials between GRAIL and Illumina, GRAIL would enjoy bigger discounts than it gets today for a lot of the materials that it has. In addition, we have conducted — just because we have a lot more experience and a bigger team, we have been able to identify vendors that provide superior cost performance points across the products that we buy, and because we have been able to do that, you know, more extensively than GRAIL has so far, there are areas where we've identified vendors that offer superior cost performance than the vendors that GRAIL would use, and so they're able to take advantage of those capabilities as well. And then as a global company, we're able to enjoy the benefits of leveraging a supply chain that is global, and so, again, that gives us access to a superior cost performance supply chain than GRAIL would have on its own". (deSouza (Illumina) Tr. 2369.)

Response to Finding No. 1162.2

The proposed finding is incomplete, misleading and unreliable based on Mr. deSouza's contradictory investigational hearing testimony, and against the weight of substantial evidence demonstrating that the claimed supply chain and operational efficiencies are neither verifiable (or quantifiable) nor merger-specific. *See, e.g.*, Response to RPFF ¶ 1157; *see also* (CCFF ¶¶ 5786-5836). Respondents ignore Mr. deSouza's re-direct testimony in which he was confronted with contradictory testimony from the investigational hearing. (deSouza (Illumina) Tr. 2427-28). [redacted]

[redacted]

As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)). Mr. deSouza's bias makes this finding inherently unreliable.

Furthermore, the weight of the evidence shows that Respondents have failed to adduce evidence sufficient to substantiate Respondents' claim that Illumina's acquisition of Grail will result in their claimed operational and supply chain efficiencies, as they are not verifiable (CCFF ¶¶ 5786-5799), not merger-specific (CCFF ¶¶ 5800-5836), and have not accounted for any costs associated with achieving them. (CCFF ¶¶ 5798, 5799). Therefore, this Court should disregard the proposed finding.

> 1162.3 Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "[D]uring the due diligence process, we identified common suppliers for core components of the Galleri assay. Again, these are common to components that Illumina purchases today at a very large scale, a very large volume. . . The cost reductions associated with volume that Illumina benefits from could be shared with

GRAIL as part of an integrated company. Therefore, the cost of goods for the Galleri test would decrease". (Aravanis (Illumina) Tr. 1960–61.)

Response to Finding No. 1162.3

The proposed finding is misleading and controverted by the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable and merger-specific. In short, Respondents' supply chain and operational efficiencies are not cognizable because they have failed to demonstrate that the cost savings could not be achieved by Grail alone (CCFF ¶¶ 5800-5836) and have not accounted for any costs associated with achieving them. (CCFF ¶¶ 5798, 5799). In short, the proposed finding is contradicted by the weight of substantial record evidence demonstrating that the claimed operational and supply chain efficiencies are not verifiable (CCFF ¶¶ 5786-5799) and not merger-specific (CCFF ¶¶ 5800-5836). Therefore, this Court should disregard the proposed finding.

1162.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "Illumina and GRAIL both buy significant amounts of reagents and chemicals from third parties. That supply chain is very deep. It goes all the way back to primary formulations of products. Together, we'd have the ability to combine volumes and, therefore, reduce the prices that we paid for those reagents, because many of the reagents are common in the kind of tests that GRAIL runs versus some of the tests that Illumina runs. We also would have the ability to have increased purchasing power. So at times where supplies are constrained, like they were during the COVID era — continuing, in fact — we would have more purchasing power as a combined entity than either of us would as individual entities". (Flatley (Illumina) Tr. 4085.)

Response to Finding No. 1162.4

The proposed finding should be disregarded based on self-serving testimony, that it is misleading, and is controverted by the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable and merger-specific. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary

interest in this transaction, Mr. Flatley's testimony is inherently biased. Furthermore, the proposed finding is misleading and against the weight of the evidence as Respondents' supply chain and operational efficiencies are not cognizable because they have failed to demonstrate that the cost savings could not be achieved by Grail alone (CCFF ¶¶ 5800-5836) and have not accounted for any costs associated with achieving them. (CCFF ¶¶ 5798, 5799). In short, the proposed finding is contradicted by the weight of substantial record evidence demonstrating that the claimed operational and supply chain efficiencies are not verifiable (CCFF ¶¶ 5786-5799) and not merger-specific (CCFF ¶¶ 5800-5836). Therefore, this Court should disregard the proposed finding.

1162.5 Hans Bishop, CEO of GRAIL, testified that "As part of Illumina, I think we'll scale faster, and scale brings cost benefits." (Bishop (GRAIL) Tr. 1404.)

Response to Finding No. 1162.5

The proposed finding is inherently speculative, misleading, and against the weight of the evidence. First, Mr. Bishop speculated that he "think[s]," as part of Illumina, that Grail will "scale faster," but that is just his conjecture and far short of the requisite showing necessary for efficiencies to be deemed cognizable. The proposed finding is misleading and against the weight the evidence as Respondents' supply chain and operational efficiencies are not cognizable because they have failed to demonstrate that the cost savings could not be achieved by Grail alone (CCFF ¶¶ 5800-5836) and have not accounted for any costs associated with achieving them. (CCFF ¶¶ 5798, 5799). In short, the proposed finding is contradicted by the weight of substantial record evidence demonstrating that the claimed operational and supply chain efficiencies are not verifiable (CCFF ¶¶ 5786-5799) and not merger-specific (CCFF ¶¶ 5800-5836). Therefore, this Court should disregard the proposed finding.

1162.6 Complaint Counsel did nothing on cross examination to undermine this testimony; nor did it offer any fact witness testimony to the contrary.

Response to Finding No. 1162.6

The proposed finding is incorrect, misleading, and contradicted by the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable and merger-specific. There are numerous instances in which Complaint Counsel has elicited testimony from Respondents' witnesses that cast serious doubt on the verifiability and merger specificity of the claimed operational and supply chain efficiencies: (a) during the March 30, 2021, Illumina Rule 2.7(h) investigational hearing, Dr. Aravanis testified that Illumina's quantification of the claimed supply chain and laboratory operation efficiencies was prepared in the week prior to his testimony. (CCFF ¶ 5788); (b) [redacted]; (c) Grail is building a second laboratory "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (Bishop (Grail) Tr. 1377-78); (d) [redacted]

[redacted]

[redacted] All of these facts cited above support the proposition that Illumina's claimed lab and supply chain efficiencies are not verifiable (or quantifiable) and not merger-specific. These are just a handful of examples of the substantial evidence demonstrating that the claimed operational and supply chain efficiencies are not verifiable (CCFF ¶¶ 5786-5799) and not merger-specific (CCFF ¶¶ 5800-5836). Therefore, this Court should disregard the proposed finding.

1162.7 Evidence of this efficiency is therefore unrefuted.

Response to Finding No. 1162.7

The proposed finding is egregiously incorrect, unsupported, and controverted by the weight of substantial evidence demonstrating that the claimed operational and supply chain efficiencies are not only refuted, but they are also demonstrably not verifiable (CCFF ¶¶ 5786-5799) and not merger-specific (CCFF ¶¶ 5800-5836); *see also* Response to RPFF ¶ 1162.7. Therefore, this Court should disregard the proposed finding.

1163. Illumina has significant experience managing laboratories that operate NGS tests at scale.

Response to Finding No. 1163

The proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable and merger-specific. Although several Respondent witnesses, including Mr. deSouza and Dr. Aravanis, provided testimony that they expected to realize vague scale benefits, *none* testified as to the magnitude of such efficiencies or the inputs and assumptions necessary to estimate the magnitude of such efficiencies. It is clear, from the record evidence, that the likelihood and magnitude of the claimed efficiencies are not verifiable. (CCFF ¶¶ 5786-5799). [redacted]

[redacted]

Furthermore, record evidence shows that these supply chain and operational efficiency claims were only developed in the course of litigation, and accordingly, merit further skepticism. In particular, Respondents did not include efficiencies related to supply chain and laboratory operations in their Answer. (CCFF ¶ 5786.) Further, in [redacted]

[redacted]

Respondents also failed to demonstrate that the supply chain and operational efficiencies are merger specific. (CCFF ¶¶ 5800-5836). Respondents' expert, Dr. Carlton, did not perform an analysis to determine whether the supply chain and operational efficiencies claimed by Illumina are merger specific. (CCFF ¶ 5800). Further, the record evidence shows that these efficiencies are not merger specific because they could be achieved by Grail on its own. As a result of internal initiatives, (CCFF ¶¶ 5801-5834), Grail projected [redacted] Finally, Respondents' supply chain and operational efficiencies are not cognizable because Respondents have not accounted for any costs associated with achieving them. (CCFF ¶¶ 5798, 5799). Therefore, this Court should disregard the proposed finding.

> 1163.1 As Francis deSouza explained, Illumina has been operating laboratories at scale "for well over a decade now. We have labs in the U.S. but also outside the U.S. . . Our labs have already been delivering tests in the millions of tests a year to consumers and have been doing that for a while". (deSouza (Illumina) Tr. 2371.)

Response to Finding No. 1163.1

The proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Response to RPFF ¶ 1163. Therefore, this Court should disregard the proposed finding.

> 1163.2 Illumina operates genomic tests for cancer therapy selection, genetic disease diagnosis and other uses. (deSouza (Illumina) Tr. 2371.)

Response to Finding No. 1163.2

The proposed finding is misleading and against the weight of the evidence to the extent

Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Response to RPFF ¶ 1163. Therefore, this Court should disregard the proposed finding.

> 1163.3 Illumina has also optimized its work flow from a cost and safety perspective. (deSouza T. 2371–72; *see also* Aravanis (Illumina) Tr. 1961–62 ("Illumina has developed automation capabilities to automate assays and reduce cost. It's also developed the capabilities to dynamically staff large sequencing operations and by doing so reducing labor costs associated with that. It's also developed the ability to efficiently use real estate and laboratories".).)

Response to Finding No. 1163.3

The proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Response to RPFF ¶ 1163. Illumina has not accounted for [redacted]

[redacted] As Grail's CEO testified at trial, Grail built the RTP laboratory both to "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (CCFF ¶ 5808). As a result of these initiatives, Grail projected [redacted]

Furthermore, as an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)). Mr. deSouza's bias makes this finding inherently unreliable. Therefore, this Court should disregard the proposed finding.

1164. GRAIL, in contrast, only has one laboratory and limited experience operating that lab. (deSouza (Illumina) Tr. 2370; Bishop (GRAIL) Tr. 1376; Aravanis (Illumina) Tr. 1892.)

Response to Finding No. 1164

The proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Responses to RPFF ¶¶ 1163, 1163.3. Therefore, this Court should disregard the proposed finding.

1165. Combining Illumina and GRAIL will allow GRAIL to benefit from Illumina's lab operations capabilities.

Response to Finding No. 1165

The proposed finding is wholly unsupported and should be disregarded for this reason. In addition, the proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Responses to RPFF ¶¶ 1163, 1163.3. Therefore, this Court should disregard the proposed finding.

1165.1 Undisputed fact testimony established this efficiency.

Response to Finding No. 1165.1

The proposed finding is wholly unsupported and should be disregarded for this reason. In addition, the proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6 (pointing to fact witness testimony in particular that casts doubt on the claimed supply chain and operational efficiencies), 1163, 1163.3. Therefore, this Court should disregard the proposed finding.

> 1165.2 Francis deSouza, CEO and President of Illumina, testified that: "[W]e already have the lab facilities, the real estate facilities. We already have the equipment in the labs. We already have the personnel that are trained to run genomics, and it requires a certain level of sophistication to run a genomics pipeline. In addition to that, we have optimized the work flows associated with running a genomics lab, things like that sample accessioning, how do you bring in, you know, from a logistics perspective but then also, on the facility itself, how do you unpack a lot of samples? How do you maintain a chain of custody with integrity as a sample comes in to your position all the way, you know, until you return data? We have also been able to optimize the work flow end to end from a safety perspective, from a supply chain — sorry, chain of custody perspective, and from a cost perspective. We've also developed the custom automation tools it takes to run a highly automated lab. We've also developed the software pipeline it takes to analyze the data in a very high throughput way coming off those samples. So, you know, all of those operational capabilities are benefits that GRAIL will enjoy, and it will take GRAIL years to develop that capability themselves" (deSouza (Illumina) Tr. 2371–72.)

Response to Finding No. 1165.2

The proposed finding is misleading and against the weight of the evidence to the extent

Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1163.3.

Mr. deSouza's bias also makes this finding inherently unreliable and should be disregarded for this reason. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)).

Further, the record evidence shows that these efficiencies are not merger specific because they could be achieved by Grail on its own. For example, at the time of the Transaction, [redacted]

[redacted] As Grail's CEO testified at trial, Grail built the RTP laboratory both to "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (CCFF ¶ 5808). As a result of these initiatives, Grail projected [redacted]

> 1165.3 Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "So Illumina has developed automation capabilities to automate assays and reduce cost. It's also developed the capabilities to dynamically staff large sequencing operations and by doing so reducing labor costs associated with that. It's also developed the ability to efficiently use real estate and laboratories. We believe that will lower the facilities costs that GRAIL will incur, and those, again, costs can be passed on to people purchasing the test". (Aravanis (Illumina) Tr. 1961.)

Response to Finding No. 1165.3

The proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2. In addition, the proposed finding is inherently speculative, as Dr. Aravanis testified that he "believe[s] that will lower the facilities costs that GRAIL will incur,"

but this does not account for what Grail could have achieved on its own as well as it does not account for the costs that Illumina will incur to achieve the claimed efficiencies. Therefore, this Court should disregard the proposed finding.

> 1165.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "Well, both companies run laboratories. GRAIL has one. Illumina has several of these around the world. And to the extent that we could integrate those lab operations, we would have much more consistent protocols, much more consistent software, both on the — how we bring samples into the laboratory and how we control the samples and build the databases around the sample information, but also on the reporting side, as well as the what are called lab information management systems, which control sample processing through the overall laboratory. Separate, those systems would be very divergent, and patients would get different types of reports, and the sample control and the data sets would be independent. In a combined company, we would have the ability to integrate that in a very important way and leverage the data across multiple tests for a given patient and have much more unified software structures and reporting". (Flatley (Illumina) Tr. 4086.)

Response to Finding No. 1165.4

The proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable (CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2. In addition, as a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Therefore, this Court should disregard the proposed finding.

> 1165.5 Hans Bishop, CEO of GRAIL testified that "Illumina has established operations and the relevant teams of experts and laboratories in certain instances in many countries around the world" that will help GRAIL scale. (Bishop (GRAIL) Tr. 1405.)

Response to Finding No. 1165.5

The proposed finding is misleading and against the weight of the evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable

(CCFF ¶¶ 5786-5799) and merger-specific. (CCFF ¶¶ 5800-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2. Mr. Bishop testified at trial that integration planning between Illumina and Grail has not started and thus any claimed efficiencies at this stage are inherently speculative. (Bishop (Grail) Tr. 1425). Further, the record evidence shows that these efficiencies are not merger specific because they could be achieved by Grail on its own. For example, at the time of the Transaction, [redacted] As Grail's CEO testified at trial, Grail built the RTP laboratory both to "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (CCFF ¶ 5808).

As a result of these initiatives, Grail projected [redacted]

[redacted]

1165.6 Here again, Complaint Counsel failed to undermine this testimony in cross and it offered no fact witness testimony to the contrary.

Response to Finding No. 1165.6

The proposed finding is incorrect, misleading, and against the weight of substantial evidence to the extent Respondents suggest that their claimed supply chain and operational efficiencies are verifiable and merger-specific. (CCFF ¶¶ 5786-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2. There are numerous instances in which Complaint Counsel has elicited testimony from Respondents' witnesses that cast serious doubt on the verifiability and merger specificity of the claimed operational and supply chain efficiencies: (a) during the March 30, 2021, Illumina Rule 2.7(h) investigational hearing, Dr. Aravanis testified that Illumina's quantification of the claimed supply chain and laboratory operation efficiencies was prepared in the week prior to his testimony. (CCFF ¶ 5788); (b) [redacted]; (c) Grail is building a second

laboratory "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (Bishop (Grail) Tr. 1377-78); (d) [redacted] All of these facts cited above support the proposition that Illumina's claimed lab and supply chain efficiencies are not verifiable (or quantifiable) and not merger-specific. These are just a handful of examples of the substantial evidence demonstrating that the claimed operational and supply chain efficiencies are not verifiable (CCFF ¶¶ 5786-5799) and not merger-specific (CCFF ¶¶ 5800-5836). Therefore, this Court should disregard the proposed finding.

1166. Illumina has quantified the monetary cost savings from supply chain and operational efficiencies as at least $140M over a 10–year period. (RX6000 (Carlton Trial Dep. at 71); PX2613 (Illumina) at 4.) The government offered no evidence to the contrary.

Response to Finding No. 1166

The proposed finding is incorrect—Complaint Counsel has offered voluminous evidence that the claimed cost savings from supply chain and operational efficiencies are not verifiable and not merger specific. (CCFF ¶¶ 5786-5836). Furthermore, the proposed finding is incomplete and misleading to the extent Respondents suggest this is evidence that demonstrates

that the claimed supply chain and operational efficiencies are verifiable. [redacted] Dr. Carlton also testified that he is not the source of the claim that Illumina will achieve supply chain and operational efficiencies, that he did not account for any costs associated with Illumina and Grail working to achieve supply chain and operational efficiencies, and he did not independently attempt to quantify any costs associated with achieving these claimed efficiencies. (CCFF ¶¶ 5796, 5798-99). Although several Respondent witnesses indeed provided testimony that they expected to realize vague scale benefits, none testified as to the magnitude of such efficiencies or the inputs and assumptions necessary to estimate the magnitude of such efficiencies. Therefore, the lay witness testimony provided no additional substantiation for the estimated savings. This Court should disregard the proposed finding.

1167. The supply chain and operational efficiencies are unrefuted.

Response to Finding No. 1167

The proposed finding is incorrect and unsupported. Complaint Counsel has offered voluminous evidence that the claimed cost savings from supply chain and operational efficiencies are not verifiable and not merger specific. (CCFF ¶¶ 5786-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2, 1166. Therefore, this Court should disregard the proposed finding.

> 1167.1 Complaint Counsel does not dispute that supply chain and operational efficiencies may arise from a vertical transaction.

Response to Finding No. 1167.1

Complaint Counsel does not disagree that supply chain and operational efficiencies *may* arise from a vertical transaction. The substantial weight of the evidence demonstrates that Respondents have failed to substantiate the likelihood, magnitude, merger-specificity, and costs of these claimed efficiencies in this transaction such that it is possible to verify them by reasonably means. (CCFF ¶¶ 5786-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2, 1166.

> 1167.2 Nor did it call any witness to dispute the testimony from Illumina and GRAIL witnesses.

Response to Finding No. 1167.2

The proposed finding is entirely unsupported and thus should be disregarded. Furthermore, the proposed finding is incorrect and misleading as Complaint Counsel has shown that Respondents have failed to substantiate the likelihood, magnitude, merger-specificity, or costs of these claimed efficiencies in this transaction such that it is possible to verify them by reasonably means. (Complaint Counsel's Post-Trial Reply Brief at Section V.); (CCFF ¶¶ 5786-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2, 1166. Therefore, this Court should disregard the proposed finding.

1167.3 [redacted]

Response to Finding No. 1167.3

[redacted]

1167.4 However, Respondents do not depend on either Dr. Carlton or the document he cited for this efficiency.

Response to Finding No. 1167.4

The proposed finding is wholly unsupported and should be disregarded for this reason.

In addition, the proposed finding is incorrect, misleading, and against the weight of the evidence

demonstrating that Respondents have failed to substantiate the likelihood, magnitude, merger-specificity, or costs of these claimed efficiencies in this transaction such that it is possible to verify them by reasonably means. (CCFF ¶¶ 5786-5836); *see also* Responses to RPFF ¶¶ 1157, 1162.6, 1163, 1165.2, 1166. Although several Respondent witnesses indeed provided speculative testimony that they expected to realize vague scale benefits, *none* testified as to the magnitude of such efficiencies or the inputs and assumptions necessary to estimate the magnitude of such efficiencies. Therefore, the lay witness testimony provided no additional substantiation for the estimated savings. This Court should disregard the proposed finding.

1167.5 [redacted] and did not independently assess any other evidence regarding this efficiency, including the direct testimony regarding these efficiencies outlined above. (RX3854 (Rothman Dep. at 74–78); [redacted]

Response to Finding No. 1167.5

[redacted]

[redacted]

2. The Reunion of Illumina and GRAIL Will Accelerate the International Expansion of Galleri.

1168. The Transaction will accelerate the international expansion of Galleri because it will put Illumina in a position to leverage its significant international resources for GRAIL.

Response to Finding No. 1168

The proposed finding is wholly unsupported and should be disregarded on that basis. The proposed finding is also misleading and against the weight of the evidence showing that the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, nor would be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). Here, the relevant geographic market is the United States. (CCFF ¶¶ 831-885). Thus, on

its face, Respondents' claim that the transaction will "accelerate the international expansion of Galleri" is irrelevant as alleged benefits which occur outside the United States cannot offset competitive harm within the United States. And any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it.

Respondents produced no evidence regarding which specific countries the international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion would only be achieved through a merger with Illumina. Instead, record evidence shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and has not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42). Therefore, this Court should disregard the proposed finding.

> 1168.1 Complaint Counsel did not present any fact witnesses or evidence to rebut the testimony of Respondents' fact witnesses on this efficiency.

Response to Finding No. 1168.1

The proposed finding is wholly unsupported and should be disregarded on that basis. The proposed finding is also misleading and against the weight of the evidence showing that the acceleration of international testing and expansion of Galleri is neither verifiable, merger

specific, nor would be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF ¶ 1168. Thus, on its face, Respondents' claim that the transaction will "accelerate the international expansion of Galleri" is irrelevant as alleged benefits which occur outside the United States cannot offset competitive harm within the United States. And any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it.

Respondents produced no evidence regarding which specific countries the international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion would only be achieved through a merger with Illumina.

Instead, Complaint Counsel can point to record evidence showing that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he neither quantified the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42). Therefore, this Court should disregard the proposed finding.

> 1168.2 Illumina has a strong international presence with platforms and/or tests registered in over 140 countries around the world. (deSouza (Illumina) Tr. 2374; PX6066 (Illumina).)

Response to Finding No. 1168.2

The proposed finding is irrelevant, misleading, and against the weight of the evidence

showing that the acceleration of international testing and expansion of Galleri is neither verifiable or merger specific, nor would be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF ¶ 1168. Any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it. Instead, record evidence shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42). Therefore, this Court should disregard the proposed finding.

> 1168.3 As Mr. deSouza explained, "[Illumina has] a strong international presence. In fact, more than half of Illumina's revenue today comes from outside the U.S., and so the countries outside the U.S. represent the majority of Illumina's business today . . . Today, we've placed products in over 140 countries around the world. We have clear products in dozens of countries around the world. . . . We have partners, we have sales teams, we have in-market surveillance teams to make sure that we are quick to recognize if there's any issue our customers are having and be able to respond. We're able to market into those countries". (deSouza (Illumina) Tr. 2374; PX6066 (Illumina).)

Response to Finding No. 1168.3

The proposed finding is irrelevant, misleading, and against the weight of the evidence showing that the acceleration of international testing and expansion of Galleri is neither verifiable, merger specific, or would be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF ¶ 1168. Any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not

establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it. Instead, record evidence shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42). Therefore, this Court should disregard the proposed finding.

> 1168.4 Illumina has significant experience working with foreign regulators and payors and with obtaining regulatory approvals. (deSouza 2374; Febbo (Illumina) Tr. 4351–52.)

Response to Finding No. 1168.4

The proposed finding is irrelevant, misleading, and against the weight of the evidence showing that the acceleration of international testing and expansion of Galleri is neither verifiable, merger specific, or would be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF ¶ 1168.

The proposed finding is irrelevant because alleged out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it. Instead, record evidence shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did

not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42).

In addition, Mr. deSouza's bias makes this finding inherently unreliable. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)).

Furthermore, Mr. deSouza does not have the foundation to testify as to Illumina's comparative ability to bring the Galleri test to international markets. [redacted] Mr. deSouza also does not have knowledge of Grail's employee expertise. (deSouza (Illumina) Tr. 2419). Therefore, this Court should disregard the proposed finding.

1169. GRAIL has no presence outside of the United States and the United Kingdom. (Freidin (GRAIL) Tr. 3008–09 ("GRAIL has been focused on the U.S. domestic market. We do have a study in the U.K. with the NHS. Other than that, our long-range plan for the next ten years, you know, really ignores anything international. We don't have any international operations other than, you know, 10–20 people in the U.K. to facilitate the NHS study".); RX3282 (GRAIL).)

Response to Finding No. 1169

The proposed finding is irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that that Illumina will assist in the international expansion of Galleri; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant

market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF ¶ 1168. The proposed finding is irrelevant because alleged out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it. Instead, record evidence shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Therefore, this Court should disregard the proposed finding.

> 1169.1 Due to its limited international presence, GRAIL has not made plans to expand internationally in the near future and in fact has been unable to accept offers to provide its Galleri product to other countries due to a lack of capacity. (Freidin (GRAIL) Tr. 3009 ("Q. And what ability do you have to develop international sales today? A. Yeah. So we've got a very small corporate development team of three people, and we — we have people — we have enough people to talk to people but not enough to actually do anything, so we've often in a position of people reaching out to do things and us, you know, being polite and having to say we just can't take it on right now".).)

Response to Finding No. 1169.1

The proposed finding is irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that that Illumina will assist in the international expansion of Galleri; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842); *see also* Responses to RPFF ¶¶ 1168-69. Therefore, this Court should disregard the proposed finding.

1170. Through the proposed transaction, Illumina will dramatically increase GRAIL's ability to access international markets and to achieve regulatory and payor approvals outside the United States.

Response to Finding No. 1170

The proposed finding is wholly unsupported, irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that that Illumina will assist in the international expansion of Galleri; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842); *see also* Responses to RPFF ¶¶ 1168-69. Therefore, this Court should disregard the proposed finding.

1170.1 The fact testimony on this score was undisputed.

Response to Finding No. 1170.1

The proposed finding is wholly unsupported, irrelevant, incorrect, and against the weight of the evidence to the extent Respondents suggest that that Illumina will assist in the international expansion of Galleri; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842); *see also* Responses to RPFF ¶¶ 1168-69. Evidence in the record shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42). Therefore, this Court should disregard the proposed finding.

> 1170.2 Francis deSouza, CEO and President of Illumina, testified that: "I do know what impact international expansion will have on the GRAIL test. By accessing larger sample sets, by accessing the genomes from more patients or more consumers around the world, the GRAIL test will become more and more accurate, and this is a test that's based on a learning algorithm, and so accessing larger sample sets will improve the GRAIL test for people here in the U.S. In addition, accessing more diverse genomes than are available in the U.S., which you will get access to as you enter, you know, continents

> like Africa or Asia or Latin America, or even in the European Union, accessing the more diverse – the bigger biodiversity associated with those genomes will improve the test for people here in the U.S. This is a special issue in genomics because the cohorts that are used here in the U.S. to develop genomic tests are predominantly Caucasian cohorts. What that means is if you are an African-American person in the U.S. or a number of other minorities, the genomic tests just simply aren't as good for you as they are for Caucasians, and that's just a health inequity we're dealing with in the U.S. that we will be able to address more fully as we expand the cohorts to include cohorts from Africa and from Asia". (deSouza (Illumina) Tr. 2375–76.)

Response to Finding No. 1170.2

The proposed finding is unreliable, irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that Illumina will assist in the international expansion of Galleri or the international expansion will result in machine learning efficiencies; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842); *see also* Responses to RPFF ¶¶ 1168-69.

Evidence in the record shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42).

Moreover, any claimed machine learning efficiencies are neither verifiable nor merger specific. Respondents' economic expert testified that he did not quantify the machine learning efficiency, how much the acceleration of Grail's sales may improve the accuracy of Grail's assay, and that he did not identify which additional types of cancer may be detected through the alleged acceleration of Grail's sales. (CCFF ¶¶ 5845-47).

In addition, Mr. deSouza's bias makes this finding inherently unreliable. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)). Furthermore, Mr. deSouza does not have the foundation to testify as to Illumina's comparative ability to bring the Galleri test to international markets. [redacted] [redacted] Mr. deSouza also does not have knowledge of Grail's employee expertise. (deSouza (Illumina) Tr. 2419). Therefore, this Court should disregard the proposed finding.

> 1170.3 Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "The basis of the determination is, number one, our plans for making the Galleri test available in the many countries around the world that we operate, that GRAIL does not operate today, so that's our basis of the determination, that the test will be available worldwide, much faster than GRAIL could given that it has no operations in those countries. With offering that test in many countries in the world, that will generate a significant amount of testing data. We know that that testing data will be useful in payer discussions around the questions they'll have around clinical utility. We also know that that data will be useful in creating future versions of the Galleri test. We also know that that data will be useful in discussions with the FDA around FDA approval". (Aravanis (Illumina) Tr. 19666–67.)

Response to Finding No. 1170.3

The proposed finding is unreliable, irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that Illumina will assist in the international expansion of Galleri or the international expansion will result in machine learning efficiencies; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market.

(CCFF ¶¶ 5837-5842); *see also* Response to RPFF ¶ 1170.2. Dr. Aravanis's testimony is unreliable and speculative about how expanding Grail could result in generating more data that would be "useful in discussions with the FDA and FDA approval." Evidence in the record shows that the acceleration of international testing, expansion of Galleri, and any claimed machine learning efficiencies are neither verifiable nor merger specific. (CCFF ¶¶ 5837-5847). Therefore, this Court should disregard the proposed finding.

> 1170.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "Going into international markets is complicated. It requires often the setup of subsidiaries and legal entities. It requires hiring and employees and, therefore, setting up tax structures and all of the structures around how stock options get issued to employees. It's quite a complicated and expensive process to set up subsidiaries in countries around the world. Illumina has this in place in all of the major countries of the world, and GRAIL would have the ability to leverage that very directly even if the sales force were separate, which in some cases it would be. In some cases where we have distributors, distributors might sell both products directly to the customer, but the infrastructure that Illumina has in place would dramatically accelerate GRAIL's ability to bring Galleri to other markets of the world and to do that quite quickly". (Flatley (Illumina) Tr. 4087–88.)

Response to Finding No. 1170.4

The proposed finding is irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that that Illumina will assist in the international expansion of Galleri; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF ¶ 1168. The proposed finding is irrelevant because alleged out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it. Instead, record evidence shows that Illumina had not discussed acceleration of

Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42). In addition, as a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Therefore, this Court should disregard the proposed finding.

> 1170.5 Hans Bishop, CEO of GRAIL, testified that "first of all, selling Galleri more broadly, you know, outside the United States will have a series of country-specific regulatory approvals. We don't have a team today that has any experience of that. Illumina already has those people. Secondly, to supply a particular country requires you to have a business and capabilities in that country. And outside of the U.K., we don't have any offices around the world. Illumina has many. Thirdly, the financial resources and engineering expertise to build the infrastructure that's needed on top of what they already have is a much easier step than as a standalone company today with a very limited footprint outside the U.S.". (Bishop (GRAIL) Tr. 1406.).

Response to Finding No. 1170.5

The proposed finding is irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that that Illumina will assist in the international expansion of Galleri; in short, the acceleration of international testing and expansion of Galleri is neither verifiable nor merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF ¶ 1168. The proposed finding is irrelevant because alleged out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with

achieving it. Instead, record evidence shows that Illumina had not discussed acceleration of Galleri with payers outside the United States and had not analyzed how payer adoption outside the United States would impact coverage or market access in the United States. (CCFF ¶¶ 5837-39). Additionally, Respondents' economic expert conceded that he did not quantify the benefit of acceleration of international testing and expansion of Galleri nor did he estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (CCFF ¶¶ 5841-42). Therefore, this Court should disregard the proposed finding.

> 1170.6 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "GRAIL has been focused on the U.S. domestic market. We do have a study in the U.K. with the NHS. Other than that, our long-range plan for the next ten years, you know, really ignores anything international. We don't have any international operations other than, you know, 10–20 people in the U.K. to facilitate the NHS study. And you know, you compare that to, as I said, a multinational, billion-dollar-plus company with multiple products, locations all over the globe, and it's pretty obvious to me that they could accelerate us internationally if they have the infrastructure already". (Freidin (GRAIL) Tr. 3008.)

Response to Finding No. 1170.6

The proposed finding is irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that that Illumina will assist in the international expansion of Galleri; in short, the acceleration of international testing and expansion of Galleri is neither verifiable nor merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842). *See, e.g.*, Response to RPFF 1170.5. Therefore, this Court should disregard the proposed finding.

1171. International expansion will have a positive effect on Galleri's operations in the United States, because it will allow Galleri to gather data from more patients in less time and will allow Galleri to ensure a more representative and diverse dataset that can be used to accelerate clinical validation for GRAIL's PMA submission as well as provide clinical utility evidence for payor adoption and reimbursement in the United States. (deSouza (Illumina) Tr. 2375–78; Aravanis (Illumina) Tr. 1963–65.)

Response to Finding No. 1171

The proposed finding is unreliable, irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that Illumina will assist in the international expansion of Galleri or the international expansion will result in machine learning efficiencies; in short, the acceleration of international testing and expansion of Galleri is neither verifiable, merger specific, nor would be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842); *see also* Response to RPFF ¶ 1170.2. Dr. Aravanis's testimony is unreliable and speculative about how expanding Grail could result in generating more data that would be useful in any Grail PMA submission or payor adoption discussion in the United States. Evidence in the record shows that the acceleration of international testing, expansion of Galleri, and any claimed machine learning efficiencies are not verifiable or merger specific. (CCFF ¶¶ 5837-5847).

In addition, Mr. deSouza's bias makes this finding inherently unreliable. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)).

Furthermore, Mr. deSouza does not have the foundation to testify as to Illumina's comparative ability to bring the Galleri test to international markets. [redacted] Mr. deSouza also does not have knowledge of Grail's employee expertise. (deSouza (Illumina) Tr. 2419). Therefore, this Court should disregard the proposed finding.

1172. International acceleration will also help improve the Galleri test. As Francis deSouza testified: "by accessing a bigger market, you get a better test because the algorithms

continue to get refined, and you get better and better accuracy in the test the more samples you run. This is especially true if the samples are genomically diverse. . . . the benefit you get from running this test globally is not just driven by the fact that you are running more tests and that gives you more accurate performance. Running more tests in regions where there's high genomic biodiversity, you know, in Africa, for example, in Asia, for example, or even just extending from the UK into the rest of the European Union, or going into Latin America, gives you a more diverse set of genomes. That gives you a better test. And so long term, global expansion is important to the success of the MCED test in at least those two dimensions". (deSouza (Illumina) Tr. 2373.)

Response to Finding No. 1172

The proposed finding is unreliable, irrelevant, misleading, and against the weight of the evidence to the extent Respondents suggest that Illumina will assist in the international expansion of Galleri or the international expansion will result in machine learning efficiencies; in short, the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5842); *see also* Responses to RPFF ¶¶ 1168, 1170.2. Evidence in the record shows that the acceleration of international testing, expansion of Galleri, and any claimed machine learning efficiencies are not verifiable or merger specific. (CCFF ¶¶ 5837-5847).

In addition, Mr. deSouza's bias makes this finding inherently unreliable. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)).

Furthermore, Mr. deSouza does not have the foundation to testify as to Illumina's comparative ability to bring the Galleri test to international markets. [redacted]

[redacted]

[redacted] Mr. deSouza also does not have knowledge of Grail's employee expertise. (deSouza (Illumina) Tr. 2419). Therefore, this Court should disregard the proposed finding.

1173. The international acceleration efficiency is unrefuted.

Response to Finding No. 1173

The proposed finding is incorrect and against the substantial weight of the evidence showing that the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5364-5672; 5837-5847); *see also* Responses to RPFF ¶¶ 1168-1172. Moreover, Grail was already aggressively pursuing FDA approval as an independent company. (CCFF ¶¶ 5259-5363). Therefore, this Court should disregard the proposed finding.

1173.1 Complaint Counsel did not call any fact witness who undermined the testimony from Illumina and GRAIL witnesses.

Response to Finding No. 1173.1

The proposed finding is incorrect and against the substantial weight of the evidence showing that the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5847); *see also* Responses to RPFF ¶¶ 1168-1173. Therefore, this Court should disregard the proposed finding.

1173.2 [redacted]

Response to Finding No. 1173.2

[redacted]

[redacted]

1173.3 Thus, there is no actual dispute that the Transaction will accelerate international adoption of Galleri.

Response to Finding No. 1173.3

The proposed finding is incorrect and against the substantial weight of the evidence showing that the acceleration of international testing and expansion of Galleri is not verifiable, not merger specific, and would not be passed on through to consumers in the relevant market. (CCFF ¶¶ 5837-5847); *see also* Responses to RPFF ¶¶ 1168-1172. Therefore, this Court should disregard the proposed finding.

G. The Benefits of the Transaction Are Merger Specific.

1174. Each of the efficiencies arising from the Transaction is merger specific because each was not, and could not have been, achieved but for the Transaction.

Response to Finding No. 1174

The proposed finding is wholly unsupported, conclusory, incorrect, and contradicted by the substantial weight of the evidence showing that the alleged efficiencies are not merger specific. (CCFF ¶¶ 5250-5363, 5379-5674) (FDA and payer acceleration efficiency claims are not merger-specific); (CCFF ¶¶ 5678-5705) (EDM efficiency claims are not merger-specific); (CCFF ¶¶ 5752-5756) (R&D efficiency claims are not merger-specific); (CCFF ¶¶ 5757-5777) (Elimination of the Grail royalty is not merger-specific); (CCFF ¶¶ 5800-5836) (Lab and Supply Chain efficiency claims are not merger-specific); (CCFF ¶¶ 5837-5847) (International Expansion of Galleri, acceleration of other test developers' FDA approval processes, and claimed machine learning efficiencies are all not merger-specific). Therefore, this Court should disregard the proposed finding.

1175. The acceleration efficiencies are merger specific because it would not be possible to achieve these efficiencies without the Transaction.

Response to Finding No. 1175

The proposed finding is wholly unsupported, conclusory, incorrect, and contradicted by the substantial weight of the evidence showing that the alleged acceleration efficiencies are not merger specific. (CCFF ¶¶ 5250-5363, 5379-5674) (FDA and payer acceleration efficiency claims are not merger-specific); (CCFF ¶¶ 5837-5847) (International Expansion of Galleri, acceleration of other test developers' FDA approval processes, and claimed machine learning efficiencies are all not merger-specific). Respondents have failed to substantiate that Illumina actually possesses any comparative advantage over Grail such that Grail could not achieve FDA approval and payer acceptance as quickly as the merged firm. To the extent Respondents' merger-specificity argument is based on its claim that Illumina has greater financial resources,

record evidence shows that Grail would have been able to attain funding through less anticompetitive means than the Acquisition. (CCFF Section VIII.D.)

Respondents rely on vague, unsupported assertions from Mr. deSouza, Dr. Aravanis, and Dr. Ofman regarding the comparative abilities of Illumina versus Grail in support of their acceleration claims. Dr. Ofman's statements were revealed at trial to be unsupported speculation that were not based on any relevant personal knowledge. Dr. Ofman conceded on cross examination that [redacted] Dr. Ofman demonstrated at trial that was unaware of even the most basic information about Illumina's regulatory experience. He

conceded on cross examination that he: did not know how many PMA approvals Illumina had obtained or whether that number was greater than one; did not know whether the FDA approval Illumina received for its sequencer was a PMA approval or not; did not know the name of the IVD test for which Illumina had received PMA approval; did not know the date on which that approval was granted, or whether the approval had taken place within the last four years; was not familiar with the specific details of Illumina's interactions with the FDA relating to its approved IVD test; did not know how long Illumina has been attempting to secure PMA approval for its TSO-500 therapy selection test; did not know how successful or unsuccessful Illumina's efforts towards achieving approval for its TSO-500 therapy selection test have been; and could not recall the status of Illumina's efforts to obtain PMA approval for its NIPT test. (Ofman (Grail) Tr. 3450-3453).

Similarly, Respondents relied extensively on the testimony of Illumina's Chief Medical Officer, Dr. Febbo, in support of their FDA acceleration claims. But like Dr. Ofman, cross-examination of Dr. Febbo revealed that [redacted]

[redacted]

The other business executives cited by Respondents similarly failed to substantiate that their views on acceleration were more than mere unfounded speculation, such as Mr. deSouza, Dr. Aravanis, and Mr. Qadan. For example, Ammar Qadan, Illumina's Global Head of Market Access, acknowledged that [redacted] Further, Mr. Qadan testified at trial that Illumina's Market Access group does not have the budget available for the clinical studies Galleri will require. (Qadan (Illumina) Tr. 4267-68). And Grail's CEO Hans Bishop admitted that he could not quantify how much sooner he expects Grail to receive PMA approval if Grail receives assistance from Illumina versus without. (Bishop (Grail) Tr. 1426).

Similarly, Mr. deSouza's testimony that Respondents cite to is contradicted by other testimony that he does not get involved in the details of the FDA submissions and did not look through the resumes of the Grail employees and, accordingly, is unfamiliar with their expertise. (CCFF ¶¶ 5111-5112). As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259)). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza (Illumina) IHT at 259)). Mr. deSouza's bias makes this

finding inherently unreliable.

The proposed finding is also misleading and strongly against the weight of the evidence because Complaint Counsel has produced robust record evidence showing that [redacted] To date, Illumina has only received one PMA from the FDA, the type of FDA approval which would be required for Grail's Galleri test. (CCFF ¶ 5146). In contrast, numerous other have received PMA approval for IVD tests, including FMI, which has recently obtained a Class III, single-site PMA for three different NGS-based diagnostic tests and holds more Class III PMAs for NGS-based diagnostic tests than Illumina. (CCFF ¶¶ 5405-08). Illumina also lacks experience conducting the types of large-scale clinical trials that Grail, as a standalone company,

has already begun to obtain FDA approval. In fact, Illumina had to rely on a partner to sponsor the clinical study required for its own PMA approval. (CCFF ¶ 5169).

In contrast to Illumina, Grail is already pursuing FDA acceleration independently, (CCFF ¶¶ 5259-363), having created a well-established regulatory team. (CCFF ¶¶ 5291-95).

Even if Grail needed assistance outside of its own resources to achieve FDA approval and

reimbursement, Respondents have failed to demonstrate that Grail could not achieve acceleration through other less anticompetitive means than the Transaction. To the extent that Grail desires additional regulatory team experience, Grail could simply hire additional regulatory team members. As Complaint Counsel's expert Dr. Rothman testified, [redacted]

Additionally, as Aaron Freidin, Grail's Chief Financial Officer, testified, [redacted]

Further, other companies in the industry possess more experience than Illumina marshalling products through the FDA's PMA process, and thus, could provide alternatives to the Acquisition. Numerous companies, including Abbott, Becton Dickinson, Biogenex

Laboratories, Bio-Merieux, Epigenomics AG, Exact Sciences, Foundation Medicine, Gen-Probe Inc., Guardant Health, Hologic, Invivoscribe, Myriad, Roche, Siemens, and Thermo Fisher, among others, have received PMA approval for IVD tests. (CCFF ¶ 5408). Respondents cite Illumina's quality management system as one reason why they believe Illumina is uniquely positioned to assist with acceleration. But Grail's CMO, Dr. Ofman, conceded on cross examination that Illumina is not the only company with a quality management system (QMS) that meets the FDA's standards – and that, in fact, that many companies other than Illumina have quality management systems that have met with FDA approval for IVD tests. (Ofman (Grail) Tr. 3446). Additionally, FMI has recently obtained a Class III, single-site PMA for three different NGS-based diagnostic tests and holds more Class III PMAs for NGS-based diagnostic tests than Illumina. (CCFF ¶¶ 5405-07). However, Grail did not approach Abbott, Becton Dickinson, Foundation Medicine, Myriad, Roche, Thermo Fisher, or any other life sciences companies about potentially merging or partnering with Grail prior to agreeing to be purchased by Illumina. (Ofman (Grail) Tr. 3447-3448. Therefore, this Court should disregard the proposed finding.

> 1175.1 As numerous Illumina and GRAIL fact witnesses testified, Illumina's capabilities with regulatory approval, market access and international expansion are a product of years of work and cannot be easily replicated. (deSouza (Illumina) Tr. 2377–78; Aravanis (Illumina) Tr. 1947–48; Ofman (GRAIL) Tr. 3308 ("our ability to scale the business is limited if we are doing this on our own. It will take a long time. And if we're part of Illumina, I firmly believe that that time will be greatly accelerated, and so our ability to achieve our aspiration will not only be accelerated but actually, you know, fortified by being part of a company with the magnitude and the capabilities of Illumina").)

Response to Finding No. 1175.1

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that Illumina's acquisition of Grail will result in cognizable efficiencies with respect to regulatory approval, market access, and international expansion. (CCFF ¶¶ 5250-5363, 5379-5674) (FDA and payer acceleration efficiency claims are not

merger-specific); (CCFF ¶¶ 5837-5847) (International Expansion of Galleri, acceleration of other test developers' FDA approval processes, and claimed machine learning efficiencies are all not merger-specific); *see also* Response to RPFF ¶ 1175. Therefore, this Court should disregard the proposed finding.

> 1175.2 Fact witnesses with personal knowledge also testified that GRAIL could not achieve these efficiencies by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up to speed on the specific needs in a new area such as screening. (PFF ¶¶ 1175.1–1175.2.4.)

Response to Finding No. 1175.2

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that Illumina's acquisition of Grail will result in cognizable efficiencies with respect to regulatory approval, market access, and international expansion. (CCFF ¶¶ 5250-5363, 5379-5674) (FDA and payer acceleration efficiency claims are not merger-specific); (CCFF ¶¶ 5837-5847) (International Expansion of Galleri, acceleration of other test developers' FDA approval processes, and claimed machine learning efficiencies are all not merger-specific); *see also* Response to RPFF ¶ 1175. Therefore, this Court should disregard the proposed finding.

> 1175.2.1 Dr. Febbo testified that "I know through our use of consultants and our hiring of individuals into regulatory, into market access, across our personnel, is that there's just not a deep, rich bench of experience available for consultants, and the model of a consultant driving that just doesn't work as effectively as having internal employees". (Febbo (Illumina) Tr. 4365.)

Response to Finding No. 1175.2.1

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that Illumina's acquisition of Grail will result in cognizable efficiencies with respect to regulatory approval, market access, and international expansion. (CCFF ¶¶ 5250-5363, 5379-5674) (FDA and payer acceleration efficiency claims are not

merger-specific); (CCFF ¶¶ 5837-5847) (International Expansion of Galleri, acceleration of other test developers' FDA approval processes, and claimed machine learning efficiencies are all not merger-specific); *see also* Response to RPFF ¶ 1175.

Cross-examination of Dr. Febbo revealed that [redacted] Moreover, Dr. Febbo testified at trial that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45). Therefore, this Court should disregard the proposed finding.

> 1175.2.2 As Mr. Qadan explained, "you build institutional capability over time internally that might not be the subject-matter expertise of those consultants, because, again, consultants are teams that come and go, so they do not have that institutional expertise. . . . [T]hat's really the main reason why . . . a group of consultants cannot do the work with companies. And our, again, experience when we needed to use consultants even for strategy work, it has been a steep learning curve in many cases when it comes to the applications or clinical applications we're dealing with". (Qadan (Illumina) Tr. 4167–68.)

Response to Finding No. 1175.2.2

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that [redacted]

On cross-examination, Mr. Qadan, Illumina's Global Head of Market Access, acknowledged that [redacted] Further, Mr. Qadan testified at trial that Illumina's Market Access group does not have the budget available for the clinical studies Galleri will require. (Qadan (Illumina) Tr. 4267-68). Therefore, this Court should disregard the proposed finding.

1175.2.3 [redacted]

Response to Finding No. 1175.2.3

[redacted]

[redacted]

[redacted]

[redacted]

1175.2.4 [redacted]

Response to Finding No. 1175.2.4

[redacted]

[redacted]

1175.3 Finally, Illumina and GRAIL witnesses testified that they could not contract for these efficiencies if they were separate entities because Illumina does not provide such services to any third party entities and doing so would require GRAIL to share its confidential information with Illumina. (Aravanis (Illumina) Tr. 1969–70 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't necessarily – it wouldn't otherwise share".); Febbo (Illumina) Tr. 4369 ("you don't see total alignment between two companies, and nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to

improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships".); [redacted]

Response to Finding No. 1175.3

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that [redacted] In fact, [redacted] (CCFF ¶ 5349).

With respect to payer approval, [redacted]

[redacted]

Assessing whether Grail would have collaborated with Illumina or another third-party on R&D projects is irrelevant because the weight of the evidence shows that any such R&D advances could have been achieved by Grail as a standalone company. First, many of the claimed R&D "breakthroughs" have already been discovered by Grail, and simply require investment to materialize. For example, Respondents claim the Transaction [redacted], but Respondents' executives admitted at trial that Grail *already* has developed evidence that its technology can be applied to other technologies—including "fatty liver disease." [redacted] (Aravanis (Illumina) Tr. 1955). In fact, Grail already is [redacted] as well as conducting [redacted] ([redacted]). Thus, these alleged efficiencies are not merger specific because Grail could have achieved them as a standalone company.

Second, there is no evidence that Illumina has any unique assets or experience that position it as the only company that could help Grail achieve such R&D advances. With respect to financing, Grail would have been able to attain funding through less anticompetitive means

than the Acquisition. For example, prior to the Acquisition, [redacted]

Moreover, there is no record evidence that Illumina possesses any unique expertise which would allow it to assist Grail in achieving the claimed acceleration and R&D efficiencies. For example, Respondents assert that Illumina can assist Grail with R&D because [redacted]

[redacted]

1175.4 The fact testimony was corroborated by unrefuted expert testimony: As Dr. Carlton explained, the acceleration efficiencies are merger specific because:

Response to Finding No. 1175.4

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that [redacted]. Therefore, this Court should disregard the proposed finding.

1175.4.1 Illumina Does Not Offer Regulatory or Market Access Assistance to Third Parties. "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to GRAIL to help it get FDA approval or payer approval". (RX6000 (Carlton Trial Dep. at 60).)

Response to Finding No. 1175.4.1

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that [redacted] Grail neither needs Illumina's assistance in order to gain FDA approval or payer approval, nor is it likely that Illumina would assist in accelerating Grail to achieve either of these goals. Examination of the testimony cited

by Respondents reveals that Respondents failed to substantiate their acceleration claims such that it would be possible to verify the likelihood and magnitude, as well as the merger-specificity, by reasonable means. In fact, [redacted] Therefore, this Court should disregard the proposed finding.

> 1175.4.2 GRAIL Would Not Share Confidential Information. "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through". (RX6000 (Carlton Trial Dep. at 60–61).)

Response to Finding No. 1175.4.2

First, the proposed finding should be disregard because Respondents cite only to the paid testimony of Dr. Carlton that is uncorroborated by any ordinary course documents or testimony. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded. The proposed finding is also misleading and against the weight of substantial evidence to the extent Respondents suggest tha [redacted]

[redacted]

Assessing whether Grail would have collaborated with Illumina or another third-party on R&D projects is irrelevant because the weight of the evidence shows that any such R&D advances could have been achieved by Grail as a standalone company. First, many of the claimed R&D "breakthroughs" have already been discovered by Grail, and simply require investment to materialize. For example, Respondents claim the Transaction will lead to insights allowing Grail's technology to apply to other diseases, including "fatty liver disease," Respondents' Post-Trial Brief at 203, but Respondents' executives admitted at trial that Grail *already* has developed evidence that its technology can be applied to other technologies—including "fatty liver disease." [redacted] (Aravanis (Illumina) Tr. 1955). In fact, Grail already is [redacted] Thus, these alleged efficiencies are not merger specific because Grail could have achieved them as a standalone company.

Second, there is no evidence that Illumina has any unique assets or experience that position it as the only company that could help Grail achieve such R&D advances. With respect to financing, Grail would have been able to attain funding through less anticompetitive means than the Acquisition. For example, prior to the Acquisition, [redacted]

[redacted]

Moreover, there is no record evidence that Illumina possesses any unique expertise which would allow it to assist Grail in achieving the claimed acceleration and R&D efficiencies. For example, Respondents assert that Illumina can assist Grail with R&D because [redacted]

1175.4.3 Illumina and GRAIL Testimony Supports Merger Specificity. "[B]oth Mr. deSouza and Bishop have told me that this acceleration won't be achieved by, you know, just hiring consultants or outside staff". (RX6000 (Carlton Trial Dep. at 61).)

Response to Finding No. 1175.4.3

First, the proposed finding should be disregard because Respondents cite only to the paid testimony of Dr. Carlton that is uncorroborated by any ordinary course documents or testimony. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded. The proposed finding is also misleading and against the weight of substantial evidence to the extent Respondents suggest that Illumina's acquisition of Grail will result in cognizable efficiencies with respect to regulatory approval, market access, and international expansion. (CCFF ¶¶ 5250-5363, 5379-5674) (FDA and payer acceleration efficiency claims are not merger-specific); (CCFF ¶¶ 5837-5847) (International Expansion of Galleri, acceleration of other test developers' FDA approval processes, and claimed machine learning efficiencies are all not merger-specific); *see also* Responses to RPFF ¶¶ 1175, 1175.2. Therefore, this Court should disregard the proposed finding.

> 1175.5 Complaint Counsel argued the Transaction's acceleration benefits are not merger specific, but it presented no evidence to support the assertion.

Response to Finding No. 1175.5

The proposed finding is wholly unsupported, conclusory, incorrect, and contradicted by the substantial weight of the evidence showing that [redacted]

Therefore, this Court should disregard the proposed finding.

1176. Similarly, the R&D efficiencies described above are merger specific because they could not be achieved without the Transaction.

Response to Finding No. 1176

The proposed finding is wholly unsupported, conclusory, incorrect, and contradicted by the substantial weight of the evidence showing that [redacted]

First, many of the claimed R&D "breakthroughs" have already been discovered by Grail, and simply require investment to materialize. For example, Respondents claim the Transaction will lead to insights allowing Grail's technology to apply to other diseases, including "fatty liver disease," Respondents' Post-Trial Brief at 203, but Respondents' executives admitted at trial that Grail *already* has developed evidence that its technology can be applied to other technologies—including "fatty liver disease." [redacted] (Aravanis (Illumina) Tr. 1955). In fact, Grail already is [redacted] Thus, these alleged efficiencies are not merger specific because Grail could have achieved them as a standalone company.

Second, there is no evidence that Illumina has any unique assets or experience that position it as the only company that could help Grail achieve such R&D advances. With respect to financing, Grail would have been able to attain funding through less anticompetitive means than the Acquisition. For example, prior to the Acquisition, [redacted]

[redacted]

Moreover, there is no record evidence that Illumina possesses any unique expertise which would allow it to assist Grail in achieving the claimed acceleration and R&D efficiencies. For example, Respondents assert that Illumina can assist Grail with R&D because [redacted]

1176.1 Every single fact witness to address the issue testified—without exception—that it would take GRAIL years to develop the R&D capabilities Illumina has. (Aravanis (Illumina) Tr. 1967; deSouza (Illumina) Tr. 2354–57; Flatley (Illumina) Tr. 4086–87.)

Response to Finding No. 1176.1

The proposed finding is irrelevant, misleading, and contradicted by the substantial weight of the evidence showing that [redacted] There is no record evidence that Illumina possesses any unique expertise which would allow it to assist Grail in achieving the claimed acceleration and R&D efficiencies. For example, Respondents assert that Illumina can assist Grail with R&D because [redacted]

1176.2 Illumina and GRAIL could not achieve the efficiencies at issue by contract because Illumina does not offer such services to third parties and GRAIL would be unwilling to collaborate on R&D projects with a third party because doing so would require GRAIL to share its "secret sauce" with Illumina. (Febbo (Illumina) Tr. 4369–70

("without understanding in depth the specifics of the sequencing that's performed, the specifics of the bioinformatics that goes from that sequencing and pulls out the methylation patterns that – and then the machine-learning that's used to identify that cancer detection signal, to identify that tissue of origin of signal, without deeply understanding that, it's almost impossible for our scientists, who know the technology better than any other company, to realize efficiencies. So you have to get to that deep, fundamental understanding and exchange in order to realize the full benefit of coming together and the full efficiencies".);

Response to Finding No. 1176.2

The proposed finding is irrelevant, misleading, and contradicted by the substantial weight of the evidence showing that the alleged R&D efficiencies are not verifiable and not merger specific.

Respondents also cite to Illumina's Chief Medical Officer, Dr. Febbo, in support of their claimed R&D efficiencies. But cross-examination of Dr. Febbo revealed that his views on the are based on vague speculation lacking personal knowledge. For example,

[redacted]

[redacted] Furthermore, evidence that Dr. Febbo's R&D claims are speculative can be drawn from his testimony at trial when he indicated that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45). In effect, such claims are not substantiated and speculative. Therefore, this Court should disregard the proposed finding.

1176.3 Here again, the undisputed fact witness testimony is corroborated by Dr. Carlton's testimony regarding why the acceleration efficiencies are merger specific:

Response to Finding No. 1176.3

The proposed finding is unsupported, misleading, and contradicted by the substantial weight of the evidence showing that [redacted]

1176.3.1 Illumina and GRAIL Would Not Share Confidential Information With Third Parties. "[P]robably the simplest reason is it's very well established in the economics literature, it's very hard to transact in information, and those are exactly the circumstances when vertical integration makes sense. That aligns exactly with what I told you earlier about how GRAIL is worried about proprietary information". (RX6000 (Carlton Trial Dep. at 62–63).)

Response to Finding No. 1176.3.1

First, the proposed finding should be disregard because Respondents cite only to the paid testimony of Dr. Carlton that is uncorroborated by any ordinary course documents or testimony. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded. The proposed finding is also misleading and against the weight of substantial evidence to the extent Respondents suggest that [redacted]

[redacted].

The proposed finding is also contradicted by the substantial weight of the evidence showing that the [redacted] Therefore, this Court should disregard the proposed finding.

> 1176.3.2 Illumina Does Not Provide R&D Consulting Services. "Illumina does not provide R&D consulting to its clinical customers. As I've told you, GRAIL has explained that they will not share proprietary information in an arm's length negotiation with Illumina, in particular proprietary information about its machine-learning algorithm, and it is not the case, based on my understanding of the evidence, that there's any possibility that these R&D efficiencies could be achieved by contract, by hiring outside – outside people". (RX6000 (Carlton Trial Dep. at 63).)

Response to Finding No. 1176.3.2

The proposed finding should be disregard because Respondents cite only to the paid testimony of Dr. Carlton that is uncorroborated by any ordinary course documents or testimony. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded. The proposed finding is also misleading and against the weight of substantial evidence to the extent Respondents suggest that [redacted]

[redacted]

Furthermore, the proposed finding is also contradicted by the substantial weight of the evidence showing that the [redacted] Therefore, this Court should disregard the proposed finding.

> 1176.4 Following now-familiar form, Complaint Counsel presented no fact evidence that suggests that the acceleration benefits are not merger specific, and its experts did not meaningfully contend with the evidence summarized above.

Response to Finding No. 1176.4

The proposed finding is wholly unsupported, incorrect, and contradicted by the substantial weight of the evidence showing that [redacted] Therefore, this Court should disregard the proposed finding.

1177. The remaining cost-saving efficiencies are merger specific, because they too have not occurred, and would not occur, absent the Transaction.

Response to Finding No. 1177

The proposed finding is wholly unsupported, incorrect, and contradicted by the substantial weight of the evidence showing that the alleged "remaining cost-saving efficiencies" are not verifiable and not merger specific. While Respondents tout [redacted] Grail's CEO confirmed at trial

that the CVR's impact the company's P&L just "like a royalty." (Bishop (Grail) Tr. 1357).

Further, as demonstrated by record evidence, however, there are multiple reasons why the parties may not have eliminated the royalty prior to their agreement to merge, and thus, the absence of its pre-merger elimination is not "proof" of merger-specificity. Prior to the Acquisition, [redacted] however, as Illumina and Grail began discussions about a potential merger later that year. Therefore, the only conclusion to be inferred from the fact that the royalty had not been eliminated at the time of the merger agreement is merely that the parties had not yet discussed doing so; that does not mean the elimination of the

royalty is merger-specific.

Respondents also claim EDM efficiencies, but the record evidence demonstrates that [redacted] Therefore, Respondents have failed to prove that their EDM efficiency is merger-specific.

Moreover, Respondents have not shown that [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1177.1 [redacted]

Response to Finding No. 1177.1

[redacted]

[redacted]

1177.2 As explained, both Illumina and GRAIL have an incentive to eliminate double marginalization.

Response to Finding No. 1177.2

The proposed finding is wholly unsupported and should be disregarded on this basis. Second, the proposed finding is misleading, and contradicted by the substantial weight of the evidence showing that [redacted] Therefore, this Court should disregard the proposed finding.

1177.3 If it were feasible to achieve EDM through contract, Illumina and GRAIL would have already done so pre-merger.

Response to Finding No. 1177.3

The proposed finding is wholly unsupported and should be disregarded on this basis. Second, the proposed finding is misleading, and contradicted by the substantial weight of the evidence showing that the [redacted] Therefore, this

Court should disregard the proposed finding.

1177.4 The fact that they didn't is proof that there is no evidentiary basis to speculate that this efficiency would be achievable by contract absent the merger.

Response to Finding No. 1177.4

The proposed finding is wholly unsupported and should be disregarded on this basis. Second, the proposed finding is misleading, and contradicted by the substantial weight of the evidence showing that [redacted] Further, even Respondents' economic expert acknowledged that that the premerger relationship between Illumina and Grail had [redacted] Based on this evidence, [redacted]. Respondents have failed to identify the magnitude—let alone verify by reasonable means—of their claimed EDM efficiencies.

[redacted] Ultimately, it is Respondents' burden to establish the likelihood and magnitude and the EDM efficiency and Respondents have failed to demonstrate this in the face of record evidence suggesting that the merger is unlikely to result in any EDM effect. Therefore, this Court should disregard the proposed finding.

> 1177.5 [redacted] and the supply chain and operational efficiencies (RX6000 (Carlton Trial Dep. at 128) ("I'm not aware of any, you know, contracting, nor does she cite any, that's been done to achieve those efficiencies").)

Response to Finding No. 1177.5

[redacted]

[redacted]

1177.6 Dr. Scott Morton provided no reason why the parties would not have achieved these efficiencies through contract if it were feasible to do so.

Response to Finding No. 1177.6

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest that the [redacted] Therefore, this Court should disregard the proposed finding.

H. The Contentions of Complaint Counsel's Experts Miss the Mark.

1178. Complaint Counsel's only real response to the overwhelming and undisputed evidence that the Transaction will generate sizeable efficiencies is to fall back on its experts' assertions that the efficiencies are unsubstantiated.

Response to Finding No. 1178

The proposed finding is wholly unsupported, incorrect, and against the weight of substantial evidence citing to testimony and documents demonstrating that Respondents alleged efficiencies are not verifiable, not merger-specific, and not likely to be passed on to consumers. (Complaint Counsel's Post-Trial Reply Brief at Section V.); [redacted] Therefore, this Court should disregard the proposed finding.

1178.1 Complaint Counsel's experts arrive at their conclusions by weighing the evidence, crediting the testimony that fit Complaint Counsel's thesis and dismissing the

evidence that did not. (PX3852 (Scott Morton Dep. at 212) (stating that she "weighed [witness statements] according to the information they had, the role they play in the company and the type of competition in which they are engaged.").)

Response to Finding No. 1178.1

The proposed finding is incorrect and against the weight of substantial evidence demonstrating that Respondents alleged efficiencies are not verifiable, not merger-specific, and not likely to be passed on to consumers. (Complaint Counsel's Post-Trial Reply Brief at Section V.); [redacted] Therefore, this Court should disregard the proposed finding.

1179. Any continued claim that the efficiencies of the transaction were unsubstantiated is contradicted by the sworn testimony of no less than ten trial witnesses: Francis deSouza (President and CEO of Illumina), Dr. Alex Aravanis (Chief Technology Officer of Illumina and former head of R&D at GRAIL), Dr. Phil Febbo (Chief Medical Officer of Illumina), Ammar Qadan (Vice President and Global Head of Market Access at Illumina), Jay Flatley (former CEO and Chairman of the Illumina Board of Directors at the time of the Transaction), Hans Bishop (CEO of GRAIL), Dr. Joshua Ofman (Chief Medical Officer of GRAIL), Aaron Freidin (Senior Vice President of Finance at GRAIL), Chris Della Porta (Director, Growth Strategy, at GRAIL) and Dr. Arash Jamshidi (Senior Vice President of Data Sciences at GRAIL). It is also counter to the independent judgments of Illumina Board member knowledgeable about the industry: Dr. Frances Arnold (Director, Chairperson of Science and Technology and Nominating); Francis deSouza (Director, CEO), Caroline Dorsa (Director, Chair of Audit Committee), Dr. Robert Epstein (Director, Chair of Governance Committee), Jay Flatley (Chairman and former CEO), Dr. Scott Gottlieb (Director), Dr. Gary Guthart (Director, Chair of Compensation Committee), Philip Schiller (Director), Susan Siegel (Director) and John Thompson (Lead Independent Director).

Response to Finding No. 1179

This Court should disregard this proposed "finding of fact" for violating the Court's Order and 16 C.F.R. § 3.46. This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly asserted that "any continued claim that the efficiencies of the transaction were unsubstantiated is contradicted by the sworn testimony of no less than ten trial witnesses" and list numerous Illumina and Grail executives and directors. This is not a proposed finding of fact, but instead, a conclusory statement without any support and Respondents have not provided specific references to the evidentiary record. Additionally, the proposed finding is incorrect and against the weight of the evidence as previously articulated in Complaint Counsel's Post-Trial Reply Brief and Responses to Respondents' proposed findings of fact. (Complaint Counsel's Post-Trial Reply Brief at Section V.); [redacted] Therefore, this Court should disregard the proposed finding.

IX. COMPLAINT COUNSEL'S CHALLENGE TO THE TRANSACTION VIOLATES THE U.S. CONSTITUTION

A. The FTC Violates Article II.

1180. Article II of the U.S. Constitution vests "[t]he executive Power . . . in a President of the United States of America", who must "take Care that the Laws be faithfully executed". U.S. Const. Art II, § 1, cl. 1, § 3.

Response to Finding No. 1180

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same).

1181. FTC ALJs enjoy two layers of protection from the President. FTC ALJs may be removed only "for good cause established and determined by" someone other than the President, namely the Merit Systems Protection Board ("MSPB"). 5 U.S.C. § 7521(a).

Response to Finding No. 1181

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). The proposed finding is also inaccurate to the extent that it incorrectly suggests that FTC ALJs cannot be removed by the Commission.

1182. Merit System Protection Board members may be removed by the President only for "inefficiency, neglect of duty, or malfeasance in office." 5 U.S.C. § 1202(d).

Response to Finding No. 1182

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same).

1183. Neither the President, nor anyone directly responsible to him, nor even an officer whose conduct he may review only for good cause, has full control over FTC ALJs. 5 U.S.C. §§ 7521(a), 1202(d).

Response to Finding No. 1183

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 233. The proposed finding is also vague and misleading in its reference to "full control," which is undefined and misstates the standard for determining the constitutionality of removability provisions.

1184. In prior challenges under Article II, the FTC has argued that the dual-level of protection afforded to FTC ALJs is of no constitutional moment because they are not "Officers of the United States". (*See In re LabMD, Inc.*, Compl. Counsel's Opp'n to Resp't's Mot. to Amend Affirmative Defenses and to Dismiss this Proceeding, Dkt. No. 9537 (Jul. 24, 2015), 3 n.3.)

Response to Finding No. 1184

The proposed finding is misleading, inaccurate, and irrelevant. It was complaint counsel, not the Commission, who submitted the brief cited in the proposed finding. That brief makes clear that the issue of whether FTC ALJs are "Officers" arose in the context of a challenge to their appointment, not their removability. *See* Compl. Counsel's Opp'n to Resp't's Mot. to Amend Affirmative Defenses and to Dismiss this Proceeding at 3 n.3, *In re LabMD, Inc.*, No. 9537 (F.T.C. Jul. 24, 2015) ("This Court should also deny the proposed amendment as futile because Respondent's Appointments Clause challenge is without merit. *See, e.g.*, *Landry v. FDIC*, 204 F.3d 1125, 1132-34 (D.C. Cir. 2000) (holding that ALJs are not 'inferior officers' under the Appointments Clause when ALJs, like FTC ALJs, do not have authority to render final

decisions).”). Additionally, the proposed finding is irrelevant to Respondents’ challenge to the provisions governing the removability of FTC ALJs, as the Commission resolved any issues under the Appointments Clause when it “purely as a matter of discretion … ratified Judge Chappell’s appointment as a Federal Trade Commission administrative law judge and as the Commission’s Chief Administrative Law Judge.” Order Denying Resp. LabMD, Inc.’s Mot. to Dismiss, *In re LabMD, Inc.*, No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). Therefore, this Court should disregard the proposed finding.

1185. Like SEC ALJs, FTC ALJs are “Officers of the United States”. *See Lucia v. SEC*, 138 S. Ct. 2044, 2053–54 (2018); 5 U.S.C. § 3105; 16 C.F.R. § 3.42(c); 16 C.F.R. §§ 3.42(c)(9), 3.52(a)(1) (FTC ALJs); 17 C.F.R. § 201.360(a)(1) (SEC ALJs); 16 C.F.R. § 3.42(c) (FTC ALJs); 17 C.F.R. §§ 201.111, 200.14(a) (SEC ALJs).

Response to Finding No. 1185

The proposed finding should be disregarded because it is not a “finding of fact,” but rather a legal conclusion in contravention of the Part 3 Rules and this Court’s order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between “findings of fact” and “conclusions of law”); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a “fact.” *See* Resp. Post-Trial Brief at 233–34. The proposed finding is also conflicts with the Commission’s conclusion in *LabMD* that “the Appointments Clause does not apply to the hiring of Commission administrative law judges” because they are not “inferior officers[.]” Order Denying Resp. LabMD, Inc.’s Mot. to Dismiss, *In re LabMD, Inc.*, No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). Additionally, the proposed finding is irrelevant to Respondents’ challenge to the provisions governing the removability of FTC ALJs, as the Commission resolved any issues under the Appointments Clause when it “purely as a matter of discretion … ratified Judge Chappell’s appointment as a Federal Trade Commission administrative law judge and as the

Commission's Chief Administrative Law Judge." *Id.*

1185.1 Both may be "appoint[ed]" by their respective Commissions. 5 U.S.C. § 3105.

Response to Finding No. 1185.1

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp.'s Post-Trial Brief at 233–34. The proposed finding is also vague as to the meaning of "[b]oth," as well as irrelevant to Respondents' challenge to the provisions governing the removability of FTC ALJs, as the Commission resolved any issues under the Appointments Clause when it "purely as a matter of discretion … ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015).

1185.2 Both exercise significant authority pursuant to the laws of the United States, by exercising the authority needed to ensure fair and orderly adversarial hearings. 16 C.F.R. § 3.42(c) (empowering FTC ALJs to, among other things, "receive evidence", "conduct … hearings", "administer oaths", "rule upon … motions", and "regulate the course of the hearings and the conduct of the parties and their counsel").

Response to Finding No. 1185.2

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of

their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp.'s Post-Trial Brief at 233–34. The proposed finding is also vague as to the meaning of "[b]oth," as well as irrelevant to Respondents' challenge to the provisions governing the removability of FTC ALJs, as the Commission resolved any issues under the Appointments Clause when it "purely as a matter of discretion … ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015).

> 1185.3 Both take testimony, conduct trials, administer oaths, rule on motions, and regulate the course of hearings, as well as the conduct of parties and counsel. 16 C.F.R. § 3.42(c) (empowering FTC ALJs to, among other things, "receive evidence", "conduct … hearings", "administer oaths", "rule upon … motions", and "regulate the course of the hearings and the conduct of the parties and their counsel").

Response to Finding No. 1185.3

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 233–34. The proposed finding is also vague as to the meaning of "[b]oth," as well as irrelevant to Respondents' challenge to the provisions governing the removability of FTC ALJs, as the Commission resolved any issues under the Appointments Clause when it "purely as a matter of discretion … ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015).

1185.4 Both are empowered to make and file initial decisions, which may then be appealed to the respective full Commission. 16 C.F.R. §§ 3.42(c)(9), 3.52(a)(1) (FTC ALJs); *accord* 17 C.F.R. § 201.360(a)(1) (SEC ALJs).

Response to Finding No. 1185.4

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 233–34. The proposed finding is also vague as to the meaning of "[b]oth," as well as irrelevant to Respondents' challenge to the provisions governing the removability of FTC ALJs, as the Commission resolved any issues under the Appointments Clause when it "purely as a matter of discretion … ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015).

1185.5 Both "have all powers necessary" to "dispos[e] of" the proceedings over which they preside. 16 C.F.R. § 3.42(c) (FTC ALJs); *accord* 17 C.F.R. §§ 201.111, 200.14(a) (SEC ALJs).

Response to Finding No. 1185.5

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 233–34. The proposed finding is also vague as to the meaning of "[b]oth," as well

as irrelevant to Respondents' challenge to the provisions governing the removability of FTC ALJs, as the Commission resolved any issues under the Appointments Clause when it "purely as a matter of discretion … ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015).

The proposed finding is also misleading to the extent that it selectively quotes from a sentence in the Part 3 Rules, which provides in full: "Administrative Law Judges shall have the duty to conduct fair and impartial hearings, to take all necessary action to avoid delay in the disposition of proceedings, and to maintain order." 16 C.F.R. § 3.42(c).

1186. FTC ALJs have both adjudicative and policymaking functions.

Response to Finding No. 1186

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 234. The proposed finding is also incorrect, as the FTC ALJ's role is purely adjudicatory: the ALJ has no investigatory or enforcement functions, nor does the ALJ establish agency policies or priorities. *See* 15 U.S.C. § 57a; 16 CFR §§ 0.14, 1.13, 1.13(i), 1.14, 1.25, & 1.26(d).

1186.1 In addition to their adjudicative functions, FTC ALJs engage in some policymaking by conducting rulemaking proceedings, compiling the hearing record, resolving disputes, making recommendations to the Commission based on their findings and conclusions as to all relevant and material evidence, and ensuring that the rulemaking proceeds in an orderly fashion. *See* 16 C.F.R. § 1.13.

Response to Finding No. 1186.1

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 235. The proposed finding is also incorrect, as the FTC ALJ's role is purely adjudicatory: the ALJ has no investigatory or enforcement functions, nor does the ALJ establish agency policies or priorities. *See* 15 U.S.C. § 57a; 16 CFR §§ 0.14, 1.13, 1.13(i), 1.14, 1.25, & 1.26(d). None of the powers or responsibilities cited in the proposed finding can be considered policymaking.

1187. While the Commission may review an ALJ's decision, the Commission may also decide not to review an ALJ decision at all, in which case the ALJ's decision becomes final. 16 C.F.R. § 3.52(a)(1).

Response to Finding No. 1187

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 235. In addition, the proposed finding is incorrect and misleading because an FTC ALJ's initial decisions are purely recommendary and do not constitute agency actions unless and until the Commission ratifies them. *See* 16 C.F.R. § 3.51(a) (providing that initial decisions do not become final if a party timely appeals or if "the Commission shall have issued an order placing the case on its own docket for review or staying the effective date of the decision.").

1188. In the past 26 years, the FTC has never reversed a decision in which an FTC ALJ found liability. (RX3993 (Wright 2015) at 6.)

Response to Finding No. 1188

The proposed finding is vague, unsupported by reliable admissible evidence and is misleading in its selective use of data relating to FTC decisions. In support of its contention, Respondents cite written remarks made seven years ago stating: "in the past nearly twenty years" in each of the cases where a complaint has been tried by an administrative judge, "after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability." (RX3993 (Wright 2015) at 6.) This evidence is unreliable hearsay because former Commissioner Wright does not cite to the empirical data he upon which he relies to reach his conclusion. The proposed finding is vague because it neither identifies the criteria used to select the cases nor the exact time period examined. Nor can this source support the Respondents' assertion relating to the outcomes of FTC decisions "in the past 26 years," since the remarks were written in 2015 and thus cannot speak to FTC decisions rendered in the last seven years. Respondents also fail to account for cases where, for example, the Commission declined to review an initial decision or dismissed counts of a complaint. *E.g. McWane v. FTC*, 783 F.3d 814, 823 n.7 (11th Cir. 2015). Therefore, this Court should disregard the proposed finding.

1189. The FTC's dual-protection structure for ALJs vests significant governmental power in the hands of a single individual who is neither elected by the people nor controlled through the threat of removal by someone who is. *See* 5 U.S.C. §§ 7521(a), 1202(d).

Response to Finding No. 1189

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of

law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 236. The proposed finding is vague, misleading, and inaccurate in its characterization of "significant governmental power" and "controlled through the threat of removal," as FTC ALJs serve purely adjudicatory functions, make purely recommendary initial decisions, and are subject to removal by the Commission.

1190. In addition, FTC Commissioners are protected by a single-layer good cause removal provision. 15 U.S.C. § 41.

Response to Finding No. 1190

Complaint Counsel has no specific response.

B. The FTC's Internal Administrative Process Violates the Due Process Clause.

1191. Commissioners Rebecca Slaughter, Noah Phillips, Christine Wilson, and Rohit Chopra voted out the complaint against Respondents. (*See* Compl., *In re Illumina, Inc., & GRAIL, Inc.*, Dkt. No. 9401 (Mar. 30, 2021).)

Response to Finding No. 1191

Complaint Counsel has no specific response.

1192. Chairperson Khan was not on the Commission at the time the Complaint was issued, but she subsequently joined the Commission on June 15, 2021 and authorized this matter to proceed in lieu of litigation in federal court. (*See* RX4018 (FTC) at 1; 15 U.S.C. § 45(b).)

Response to Finding No. 1192

The proposed finding is misleading and inaccurate to the extent that it incorrectly suggests that Chair Khan voted to authorize FTC staff to dismiss the complaint in *FTC v. Illumina*, *Inc.*, No. 3:21cv800 (S.D. Cal.), or that this Part 3 proceeding is "in lieu of litigation in federal court." Therefore, this Court should disregard the proposed finding.

1193. Ms. Kahn's articles were presented to Respondents' experts during depositions. (PX7134 (Carlton Dep. at 55).)

Response to Finding No. 1193

Complaint Counsel has no specific response.

1194. Absent an unprecedented change in the composition of the Commission, the Commission will pass judgment on itself. *See* 16 C.F.R. §§ 3.11(a), 3.52(a)(1).

Response to Finding No. 1194

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 237. Furthermore, the proposed finding is vague and unclear because it fails to define what constitutes an "unprecedented change" or what is meant by the Commission "pass[ing] judgment on itself."

1195. Four of the five Commissioners participated in the prosecution of this case by interviewing witnesses and rejecting settlement offers by Respondents prior to filing the complaint.

Response to Finding No. 1195

The proposed finding is misleading and inaccurate. The conduct of the Commissioners before authorizing a complaint in this matter does not constitute "participat[ion] in the prosecution of this case," as there was not yet a "case" to "prosecute" and advocacy in support of the complaint are undertaken by certain FTC staff and not Commissioners. Therefore, this Court should disregard the proposed finding.

> 1195.1 Commissioners Rebecca Slaughter, Noah Phillips, Christine Wilson, and Rohit Chopra each individually sought out witnesses and made judgments about their credibility before voting out the complaint in both the FTC and federal court. (*See* RX0496 (FTC) at 3; RX0497 (FTC) at 1; RX0498 (FTC) at 1–2; RX0499 (FTC) at 1; RX0500 (FTC) at 2; RX0501 (FTC) at 3; Compl., *In re Illumina, Inc., & GRAIL, Inc.*, Dkt. No. 9401 (Mar. 30, 2021).)

Response to Finding No. 1195.1

The proposed finding is misleading, inaccurate, and mischaracterizes record evidence. None of the Commissioners "sought out witnesses"; as the evidence cited by Respondents shows, outside counsel for a third party requested to meet with each of the Commissioners, whose staff subsequently arranged scheduling for the requested meetings. It was therefore that outside counsel, not any Commissioner, who initiated contact and requested meetings. There is no support, in the evidence cited by Respondents or otherwise, for Respondents' assertion that any Commissioner "made judgments" about any person's "credibility." Therefore, this Court should disregard the proposed finding.

> 1195.2 Interviewing witnesses is precisely what prosecutors are authorized to do and what judges are prohibited from doing. ABA Standards for Criminal Justice § 3–3.4(c) ("The prosecutor . . . should seek to interview all witnesses"); Model Code of Jud. Conduct r. 2.9 (Am. Bar. Ass'n 2020) ("A judge shall not investigate facts in a matter independently . . . .").

Response to Finding No. 1195.2

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 237–38. The proposed finding is also incorrect and misleading. The model code of conduct cited by Respondents does not support the broad assertion that all "judges are prohibited" from meeting with a third party under any circumstances. A pre-complaint meeting with a person who may have knowledge of relevant facts in a matter does not support an inference of bias or prejudgment. *See Withrow v. Larkin*, 421 U.S. 35, 55 (1975) ("The mere exposure to evidence presented in nonadversary investigative procedures is insufficient in itself to impugn the fairness of the board members at a later adversary hearing.").

1195.3 Before filing complaints in the FTC and federal court, all four of the Commissioners at the time also acted as prosecutors by rejecting Illumina's efforts to resolve the case and instead insisting on proceeding to trial. (*See* Mot. for Conference to Facilitate Settlement, 3–4; Fed. R. Crim. P. 11(c)(1) ("An attorney for the government . . . may discuss and reach a plea agreement. The court must not participate in these discussions").)

Response to Finding No. 1195.3

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 238. The proposed finding is also incorrect and misleading. The assertion that Commissioners have "acted as prosecutors" mistakenly ignores the role that judges have in considering, facilitating, and accepting settlement agreements and plea agreements. *See, e.g.*, 15 U.S.C. § 16(e) ("Before entering any consent judgment proposed by the United States under this section, the court shall determine that the entry of such judgment is in the public interest."); *id.* § 16(f) ("In making its determination under subjection (e), the court may … take testimony of Government officials or experts or such other expert witnesses … [and] take such other action in the public interest as the court may deem appropriate."); Fed. R. Crim. P. 11(c)(3) (providing that for most categories of plea agreements, "the court may accept the agreement, reject it, or defer a decision until the court has reviewed the presentence report").

1195.4 Commissioners Rebecca Slaughter, Noah Phillips, Christine Wilson, and Rohit Chopra rejected settlement offers by Respondents prior to filing the complaint and instead insisted on proceeding to trial. ([redacted]; RX3155 (Illumina) at 1–7; Compl. at 1–2, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 14; Compl. Counsel's Mem. in Opp. to Resp'ts' Request for Expedited Consideration, Dkt. No. 9401 (July 15, 2021) at 1.)

Response to Finding No. 1195.4

[redacted]

1195.5 In July 2021, Respondents moved this administrative tribunal to convene a settlement conference to facilitate a negotiated resolution to the dispute. (*See* Resp'ts' Mot. for Conference to Facilitate Settlement, Dkt. No. 9401 (July 2, 2021) at 3–4.)

Response to Finding No. 1195.5

The proposed finding is misleading and inaccurate, because the circumstances of the filing of Respondents' motion indicated that—far from being a good-faith offer to engage in productive settlement negotiations—it was merely "a strategic move designed to give them a tactical advantage, and, if granted, would result in a waste of the Court's time." Compl. Counsel's Opp'n to Mot. for Conf. to Facilitate Settlement at 5, *In re Illumina, Inc. & Grail, Inc.*, No. 9401 (F.T.C. July 20, 2021). Therefore, this Court should disregard the proposed finding.

1195.6 Complaint counsel opposed that motion, declaring any settlement conference "a waste of time". (Compl. Counsel's Mem. in Opp. to Resp'ts' Request for Expedited Consideration, Dkt. No. 9401 (July 15, 2021) at 1.)

Response to Finding No. 1195.6

Complaint Counsel has no specific response.

1196. All of the Commissioners agreed to withdraw the federal case that would have allowed a federal district judge to decide whether the Transaction should stand, reserving that

right to themselves. (*See* RX4018 (FTC) at 1 (announcing that the Commission authorized its staff—including Complaint Counsel—to dismiss the complaint in federal court).)

Response to Finding No. 1196

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 238. The proposed finding is also misleading and inaccurate, in that it fundamentally misunderstands the role of federal court litigation under § 13(b). As Complaint Counsel argued, § 13(b) "permits the FTC to seek interim, injunctive relief to preserve the *status quo pendente lite* and protect the Commission's ability to conduct its administrative adjudicatory proceeding on the ultimate merits of whether the Defendants violated the antitrust laws." Pl.'s *Ex Parte* Application to Dismiss the Compl. Without Prejudice at 9–10, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. May 21, 2021). "The district court is not authorized to determine whether the antitrust laws have been or are about to be violated. That adjudicatory function is vested in the FTC in the first instance.'" *FTC v. H. J. Heinz Co.*, 246 F.3d 708, 714 (D.C. Cir. 2001) (quotation omitted). As such, the "only purpose of a proceeding under § 13 is to preserve the status quo until [the] FTC can perform its function." *FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976).

> 1196.1 Just as prosecutors are free to withdraw their charges at any time, Commissioners can withdraw their complaint at any time by vote rather than by a motion to withdraw or dismiss. 15 U.S.C. § 45(b).

Response to Finding No. 1196.1

The proposed finding should be disregarded because it is not a "finding of fact," but

rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 238. The proposed finding is also misleading and inaccurate. Dismissing a complaint is not an exclusively "prosecutor[ial]" function, and the statute cited by Respondents does not provide for the withdrawal or dismissal of administrative complaints.

> 1196.2 The parties agreed to work together to complete litigation over the preliminary injunction before September 20, 2021, when termination rights would kick in under the merger agreement. (*See* Opp. to FTC's Mot. to Dismiss, at 7, *Fed. Trade Comm'n v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS).)

Response to Finding No. 1196.2

The proposed finding is inaccurate, misleading, and mischaracterizes the record. FTC staff and Respondents agreed to the entry of a Temporary Restraining Order which referenced the fact that "the parties have agreed that Defendants will not close the Proposed Transaction until the earlier of September 20, 2021 or after 11:59 PM Eastern Time on the second (2nd) business day after the Court rules on Plaintiff's motion for a preliminary injunction[.]" Temporary Restraining Order, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. Mar. 31, 2021). It makes no mention of an "agreement to work together[.]" The proposed finding is also unsupported by any cite to record evidence establishing what if any "termination rights" existed under Respondents' "merger agreement." Therefore, this Court should disregard the proposed finding.

> 1196.3 To facilitate this process, the parties agreed to a temporary restraining order and commenced expedited fact discovery. **(**Plaintiff Federal Trade Commission's Unopposed Mot. for Entry of a Temporary Restraining Order, at 2, *Fed. Trade Comm'n v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS); Case Management and Scheduling Order, at 2, *Fed. Trade Comm'n v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS).)

Response to Finding No. 1196.3

The proposed finding is vague, misleading, and mischaracterizes the record. The Temporary Restraining Order speaks for itself, and Respondents fail to cite record evidence establishing what "process" the Temporary Restraining Order was intended to "facilitate[.]" Therefore, this Court should disregard the proposed finding.

> 1196.4 But only weeks before the scheduled conclusion of fact discovery, the FTC moved to dismiss its own complaint. (*See* Memo in Support of Plaintiffs' Ex Parte Application to Dismiss, *FTC v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS).)

Response to Finding No. 1196.4

The proposed finding is misleading, to the extent that it suggests that the then-forthcoming close of discovery was a factor in the decision to seek voluntary dismissal of the federal court action. The initiation of proceedings before the European Commission prohibited Respondents from closing the transaction, which therefore rendered a § 13(b) action moot. *See* Pl.'s *Ex Parte* Application to Dismiss the Compl. Without Prejudice at 10–11, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. May 21, 2021). FTC staff sought dismissal on the "assumption that Defendants will abide by the laws of all jurisdictions in which they operate"; it was only later that Respondents proved that assumption to be wrong by closing the transaction anyway. *Id.* at 8. Therefore, this Court should disregard the proposed finding.

1197. An accuser lacks the necessary neutrality to determine the merits of its own allegations.

Response to Finding No. 1197

The proposed finding should be disregarded because it is not a "finding of fact," but rather an abstract and nebulous aphorism, unsupported by any cites to record evidence. It is also misleading and inaccurate, to the extent that it impugns the impartiality of the Commission in connection with Part 3 adjudication. Section 5(b) of the FTC Act allows the Commission to

initiate "a proceeding" if the Commission "shall have reason to believe" that a person "has been or is using any unfair method of competition" and that such a proceeding "would be to the interest of the public[.]" 15 U.S.C. § 45(b). Nothing in § 5(b) requires the Commission to prejudge the outcome of such a proceeding before initiating it. To the contrary, as the Supreme Court has recognized, "just as there is no logical inconsistency between a finding of probable cause and an acquittal in a criminal proceeding, there is no incompatibility between the agency filing a complaint based on probable cause and a subsequent decision, when all the evidence is in, that there has been no violation of the statute." *Withrow v. Larkin*, 421 U.S. 35, 57 (1975).

> 1197.1 A study of SEC adjudications showed that when the SEC judged cases in which it brought charges in fiscal years 2007 through 2015, the SEC won against over 89% of defendants. (*See* RX4013 (Velikonja 2017) at 349 tbl.4.)

Response to Finding No. 1197.1

The proposed finding is irrelevant and unreliable. It is based on hearsay statements regarding a study whose reliability has not been established, and tendencies of a separate federal agency do not suggest bias or prejudgment on the part of the Commission. Therefore, this Court should disregard the proposed finding.

> 1197.2 A research project concerning potential bias at the FTC in merger challenges decided between 1956 and 1992 found that the "ability of commissioners to act as both prosecutor and judge in a particular matter can significantly increase the likelihood of a merger order". (*See* RX4014 (Coate et al 1998) at 9.)

Response to Finding No. 1197.2

The proposed finding is unreliable and mischaracterizes the nature of Part 3 adjudication. It is based on hearsay statements regarding a study whose reliability has not been established. It also mistakenly likens the role of the Commission in issuing a complaint under § 5(b) to that of a "prosecutor" rather than a "judge." The Supreme Court has recognized that "just as there is no logical inconsistency between a finding of probable cause and an acquittal in a criminal

proceeding, there is no incompatibility between the agency filing a complaint based on probable cause and a subsequent decision, when all the evidence is in, that there has been no violation of the statute." *Withrow v. Larkin*, 421 U.S. 35, 57 (1975). Therefore, this Court should disregard the proposed finding.

1197.3 A study of the legal profession found that lawyers tend to view the merits of their clients' cases too favorably. (*See* RX4015 (Eigen et al) at 1.)

Response to Finding No. 1197.3

The proposed finding is misleading, irrelevant, unreliable, and inaccurate. It is based on hearsay statements regarding a study whose reliability has not been established. It also fundamentally misunderstands Part 3 adjudication, where the Commission has no "client" and does not function as an advocate. The Commission's role in issuing complaints under § 5(b) does not suggest bias or prejudgment. To the contrary, The Supreme Court has recognized that "just as there is no logical inconsistency between a finding of probable cause and an acquittal in a criminal proceeding, there is no incompatibility between the agency filing a complaint based on probable cause and a subsequent decision, when all the evidence is in, that there has been no violation of the statute." *Withrow v. Larkin*, 421 U.S. 35, 57 (1975). Therefore, this Court should disregard the proposed finding.

1197.4 Once the Commission votes out a complaint, it finds in favor of itself 100% of the time. (RX3993 (Wright 2015) at 6.)

Response to Finding No. 1197.4

The proposed finding is vague, unsupported by reliable admissible evidence and is misleading in its selective use of data relating to FTC decisions. In support of its contention, Respondents cite written remarks made seven years ago stating: "in the past nearly twenty years" in each of the cases where a complaint has been tried by an administrative judge, "after the administrative decision is appealed to the Commission, the Commission has ruled in favor of

FTC staff and found liability." (RX3993 (Wright 2015) at 6.) This evidence is unreliable hearsay because former Commissioner Wright does not cite to the empirical data he upon which he relies to reach his conclusion. The proposed finding is vague because it neither identifies the criteria used to select the cases nor the exact time period examined. Nor can this source support the Respondents' assertion relating to the outcomes of FTC decisions "in the past 26 years," since the remarks were written in 2015 and thus cannot speak to FTC decisions rendered in the last seven years. Respondents also fail to account for cases where, for example, the Commission declined to review an initial decision or dismissed counts of a complaint. *E.g. McWane v. FTC*, 783 F.3d 814, 823 n.7 (11th Cir. 2015). Therefore, this Court should disregard the proposed finding.

> 1197.5 As former FTC Commissioner Wright stated: "The FTC has voted out a number of complaints in administrative adjudication that have been tried by administrative law judges in the past nearly twenty years. In each of those cases, after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability. In other words, in 100 percent of cases where the administrative law judge ruled in favor of the FTC staff, the Commission affirmed liability; and in 100 percent of the cases in which the administrative law judge [] found no liability, the Commission reversed. This is a strong sign of an unhealthy and biased institutional process. By way of contrast, when the antitrust decisions of federal district court judges are appealed to the federal courts of appeal, plaintiffs do not come anywhere close to a 100 percent success rate—indeed, the win rate is much closer to 50 percent." (RX3993 (Wright 2015) at 6.)

Response to Finding No. 1197.5

The proposed finding is vague, unsupported by reliable admissible evidence and is misleading in its selective use of data relating to FTC decisions. In support of its contention, Respondents cite written remarks made seven years ago stating: "in the past nearly twenty years" in each of the cases where a complaint has been tried by an administrative judge, "after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability." (RX3993 (Wright 2015) at 6.) This evidence is unreliable

hearsay because former Commissioner Wright does not cite to the empirical data he upon which he relies to reach his conclusion. The proposed finding is vague because it neither identifies the criteria used to select the cases nor the exact time period examined. Nor can this source support the Respondents' assertion relating to the outcomes of FTC decisions "in the past 26 years," since the remarks were written in 2015 and thus cannot speak to FTC decisions rendered in the last seven years. Respondents also fail to account for cases where, for example, the Commission declined to review an initial decision or dismissed counts of a complaint. *E.g. McWane v. FTC*, 783 F.3d 814, 823 n.7 (11th Cir. 2015). Therefore, this Court should disregard the proposed finding.

> 1197.6 To this day, the FTC has never decided against itself in any merger challenge. (Mot. of Resp't Axon Enter., Inc., to Stay Ex. 2A at 1–5, *In re Axon Enter., Inc.*, No. 9389 (FTC Jan. 10, 2020) (Chart of Federal Trade Commission Adjudicative Proceedings).)

Response to Finding No. 1197.6

The proposed finding is incorrect and unsupported because the cited document, itself hearsay, only purports to identify FTC administrative adjudicative proceedings for a roughly five-year period between January 1, 2015 and January 10, 2020. The Commission has on numerous occasions in its history ruled in favor of merging parties and against complaint counsel on the merits and dismissed the complaint following administrative adjudicative proceedings. *See, e.g*., *R.R. Donnelley,* 120 F.T.C. 36 (July 21, 1995); *In re Adventist Health Sys./W*., 117 F.T.C. 224 (Apr. 1, 1994); *In re Owens-Illinois, Inc.*, 115 F.T.C. 179 (Feb. 26, 1992). Therefore, this Court should disregard the proposed finding.

> 1197.7 Similarly, a former SEC Commissioner has admitted that despite needing to act with the "cold neutrality of an impartial judge" when acting in a judicial capacity, after prosecuting violations, the SEC had "a vested interest in ensuring that a particular result [was] reached [and] that particular policies [were] protected and advanced" such that "fairness and the appearance of fairness . . . [were] left behind". (RX4016 (Fleischman 1993) at 10.)

Response to Finding No. 1197.7

The proposed finding is irrelevant and unreliable. It is based on hearsay-within-hearsay statements by a former official of another agency whose reliability has not been established, and tendencies of a separate federal agency do not suggest bias or prejudgment on the part of the Commission. Therefore, this Court should disregard the proposed finding.

1198. The unusual posture of this case further highlights the way that investigative and adjudicative powers have been mingled in this case.

Response to Finding No. 1198

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 239. The proposed finding is also inaccurate and misleading, as no "investigative and adjudicative powers have been mingled" in this matter, and Respondents cite no record evidence in support of that assertion.

1198.1 Unlike most cases where the FTC has notice of a Transaction, the Transaction has already been consummated and Complaint Counsel seeks to unwind it. (*See* RX0377 (Illumina).)

Response to Finding No. 1198.1

The proposed finding is vague, misleading, and mischaracterizes record evidence. Respondents fail to define "most cases" or articulate what it means for the Commission to have "notice of a Transaction." The cited evidence does not support the proposed finding at all, nor do Respondents cite any other evidence in support of any suggestion about the commonality of challenges to consummated mergers relative to challenges to unconsummated mergers.

Therefore, this Court should disregard the proposed finding.

> 1198.2 This is no accident. Complaint Counsel initially filed a complaint in federal court seeking to enjoin the Transaction—but then unilaterally moved to dismiss its own complaint, apparently believing that the Office of Administrative Law Judges would be a friendlier forum. (*See* Compl. at 1–2, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 14; RX4018 (Press Release on FTC's Motion to Dismiss, May 2021) at 1 (announcing that the Commission authorized its staff—including Complaint Counsel—to dismiss the complaint in federal court).)

Response to Finding No. 1198.2

The proposed finding is inaccurate, misleading, and mischaracterizes record evidence. As Complaint Counsel argued, § 13(b) "permits the FTC to seek interim, injunctive relief to preserve the status quo pendente lite and protect the Commission's ability to conduct its administrative adjudicatory proceeding on the ultimate merits of whether the Defendants violated the antitrust laws." Pl.'s Ex Parte Application to Dismiss the Compl. Without Prejudice at 9–10, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. May 21, 2021). "The district court is not authorized to determine whether the antitrust laws have been or are about to be violated. That adjudicatory function is vested in the FTC in the first instance.'" *FTC v. H. J. Heinz Co., 246 F.3d 70*8, 714 (D.C. Cir. 2001) (quotation omitted). As such, the "only purpose of a proceeding under § 13 is to preserve the status quo until [the] FTC can perform its function." *FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976). The initiation of proceedings before the European Commission prohibited Respondents from closing the transaction, which therefore rendered a § 13(b) action moot. *See* Pl.'s *Ex Parte* Application to Dismiss the Compl. Without Prejudice at 10–11, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. May 21, 2021). FTC staff sought dismissal on the "assumption that Defendants will abide by the laws of all jurisdictions in which they operate"; it was only later that Respondents proved that assumption to be wrong by closing the transaction anyway. *Id.* at 8. Therefore, this Court should disregard the proposed finding.

1198.3 In its papers supporting the motion to dismiss, Complaint Counsel openly admitted that it knew Respondents did not agree that they were "prohibited from closing", and chose to dismiss its own case anyway. (*See* Pls.' Ex Parte Application to Dismiss the Compl. Without Prejudice at 5, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 120–1.)

Response to Finding No. 1198.3

The proposed finding is inaccurate, misleading, and mischaracterizes the record. The only source cited for the proposed finding, FTC staff's brief in support of its motion to dismiss the § 13(b) action, does not support it; the brief merely states: "Although Defendants appear to be appealing the EC's exercise of jurisdiction, unless either the EC completes its investigation and allows the proposed transaction to proceed, or the European General Court determines that the EC lacks jurisdiction to investigate, Defendants are prohibited from closing." *Ex Parte* Application to Dismiss the Compl. Without Prejudice at 5, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. May 21, 2021). The brief later notes that while the "FTC has invited Defendants to provide additional detail regarding the EC's process and its impact on the investigation … Defendants have steadfastly refused to provide meaningful detail … [and] have failed to correct any misunderstanding of fact or law." *Id.* at 8 n.14. FTC staff sought dismissal on the "assumption that Defendants will abide by the laws of all jurisdictions in which they operate"; it was only later that Respondents proved that assumption to be wrong by closing the transaction anyway. *Id.* at 8. Therefore, this Court should disregard the proposed finding.

1198.4 Complaint Counsel specifically reserved the right to re-file its federal action "if the [Respondents] attempt to close", but Respondents actually did close—and Complaint Counsel still chose not to re-file. (*See* Pls.' Ex Parte Application to Dismiss the Compl. Without Prejudice at 15, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 120–1.)

Response to Finding No. 1198.4

Complaint Counsel has no specific response.

> 1198.5 Then, in the middle of trial in this action, which was the first-ever challenge under the 2020 Vertical Merger Guidelines, a divided F.T.C. suddenly withdrew its own Vertical Merger Guidelines, further trying to slant the playing field in Complaint Counsel's favor by changing the rules mid-trial. (*See* RX3953 (Press Release on FTC's Withdrawal from Vertical Merger Guidelines, Sep. 2021) at 1–2.)

Response to Finding No. 1198.5

The proposed finding is inaccurate, misleading, and mischaracterizes record evidence, as it suggests that the withdrawal of the Vertical Merger Guidelines had the purpose or effect of "slant[ing] the playing field in Complaint Counsel's favor" or "changing the rules mid-trial." Neither the cited evidence nor any other evidence in the record supports that suggestion. Therefore, this Court should disregard the proposed finding.

> 1198.6 Complaint Counsel opted to try this case "on its own turf" in an administrative proceeding in which the Commission will act as the final administrative arbiter. (*See* RX3953 (Press Release on FTC's Withdrawal from Vertical Merger Guidelines, Sep. 2021) at 1–2.)

Response to Finding No. 1198.6

The proposed finding is inaccurate, misleading, and mischaracterizes record evidence. The only evidence cited is a press release announcing the withdrawal of the Vertical Merger Guidelines, which does not support any inferences about Complaint Counsel's intentions or decision-making. There is no record evidence supporting the characterization that Part 3 adjudication is Complaint Counsel's "own turf[.]" The proposed finding also fundamentally misunderstands the role of federal court litigation under § 13(b). As Complaint Counsel argued, § 13(b) "permits the FTC to seek interim, injunctive relief to preserve the status quo pendente lite and protect the Commission's ability to conduct its administrative adjudicatory proceeding on the ultimate merits of whether the Defendants violated the antitrust laws." Pl.'s Ex Parte Application to Dismiss the Compl. Without Prejudice at 9–10, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. May 21, 2021). "The district court is not authorized to determine whether

the antitrust laws have been or are about to be violated. That adjudicatory function is vested in the FTC in the first instance.'" *FTC v. H. J. Heinz Co., 246 F.3d 70*8, 714 (D.C. Cir. 2001) (quotation omitted). As such, the "only purpose of a proceeding under § 13 is to preserve the status quo until [the] FTC can perform its function." *FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976). Therefore, this Court should disregard the proposed finding.

C. The FTC's Structure and Procedural Rules Violate the Equal Protection Clause.

1199. The Equal Protection Clause of the Fifth Amendment commands that the government shall not "deny to any person within its jurisdiction the equal protection of the laws". U.S. Const. amend. XIV, § 1.

Response to Finding No. 1199

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same).

1200. The parties to a merger challenged by the FTC are treated very differently from the parties to a merger challenged by DOJ. For example:

Response to Finding No. 1200

The proposed finding is vague, irrelevant, inaccurate, misleading, and unsupported by any record evidence. Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 241. Nowhere do Respondents define what it means to be "treated very differently," nor do they cite any record evidence to support the proposed finding. Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their

outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel. Therefore, this Court should disregard the proposed finding.

1201. The parties to a merger challenged by DOJ are entitled to have the challenge adjudicated in a U.S. district court. 15 U.S.C. § 25. In contrast, the parties to a merger challenged by the FTC are not entitled to have the matter adjudicated in federal district court; they can be compelled to litigate in an internal administrative proceeding, U.S. district court, or both—at the FTC's election. 15 U.S.C. § 45(b).

Response to Finding No. 1201

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 241.

The proposed finding is also inaccurate, irrelevant, misleading, and mischaracterizes applicable law. The enforcement procedures established by Congress in the Clayton Act and the FTC Act do not create "entitlements" for respondents. As Complaint Counsel argued, § 13(b) "permits the FTC to seek interim, injunctive relief to preserve the status quo pendente lite and protect the Commission's ability to conduct its administrative adjudicatory proceeding on the ultimate merits of whether the Defendants violated the antitrust laws." Pl.'s Ex Parte Application to Dismiss the Compl. Without Prejudice at 9–10, *FTC v. Illumina, Inc.*, No. 3:21cv800 (S.D. Cal. May 21, 2021). "The district court is not authorized to determine whether the antitrust laws have been or are about to be violated. That adjudicatory function is vested in the FTC in the first instance.'" *FTC v. H. J. Heinz Co., 246 F.3d 70*8, 714 (D.C. Cir. 2001) (quotation omitted). As such, the "only purpose of a proceeding under § 13 is to preserve the status quo until [the] FTC

can perform its function." *FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976). Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1202. The parties to a merger challenged by DOJ cannot be preliminarily enjoined except upon the traditional four-part showing under the common law. Dep't of Justice, Antitrust Div., Antitrust Division Manual IV-14 (5th ed. 2012); *United States v. Gillette Co.*, 828 F. Supp. 78, 80 (D.D.C. 1993). The parties to a merger challenged by the FTC, however, can be enjoined upon a lesser showing. *See* 15 U.S.C. § 53(b)(2) ("Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, . . . a preliminary injunction may be granted"); *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 714 (D.C. Cir. 2001); RX4017 (Report of the Antitrust Modernization Commission, Apr. 2017) at 141–42.

Response to Finding No. 1202

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp.'s Post-Trial Brief at 241–42. The proposed finding is also inaccurate, irrelevant, misleading, and mischaracterizes record evidence and legal authorities. The sources cited by Respondents do not support the suggestion that the FTC can a preliminary injunction on a "lesser showing" than DOJ must make. Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019).

Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1203. The parties to a merger challenged by DOJ are guided by the Vertical Merger Guidelines. (*See* RX2598 (FTC and DOJ Vertical Merger Guidelines) at 1.) However, the parties to a merger challenged by the FTC may not be, as a majority of the current FTC Commissioners repudiated the Vertical Merger Guidelines during the pendency of this proceeding. (*See* RX3953 (Press Release on FTC's Withdrawal from Vertical Merger Guidelines, Sep. 2021) at 1–2.)

Response to Finding No. 1203

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp.'s Post-Trial Brief at 242). The proposed finding is also inaccurate and misleading, insofar as it suggests without evidence that the withdrawal of the Vertical Merger Guidelines will have an outcome-determinative effect against Respondents in this proceeding. It is also irrelevant because it is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1204. The parties to a merger challenged by DOJ are subject to a single proceeding in which DOJ has no legal recourse in the event it loses, except to appeal to the circuit court. 28 U.S.C. § 1291; Fed. R. App. P. 3(a)(1). In contrast, the parties to a merger challenged by the FTC run the risk of the FTC proceeding in two forums simultaneously (federal court and an administrative proceeding) or challenging the merger in U.S. district court and if the court rules against the challenge, retrying the entire merits proceeding in an administrative proceeding

within the FTC itself. 15 U.S.C. §§ 45(b), 53(b). The FTC possesses a significant advantage that DOJ lacks in negotiating a settlement; few parties will want to litigate a full administrative trial and face the risk of expensive and disruptive divestitures. In addition, if the FTC loses before an FTC ALJ it may reverse that decision as to both factual and legal findings. 16 C.F.R. § 3.54(b).

Response to Finding No. 1204

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 242. The proposed finding is also inaccurate, irrelevant, misleading, and unsupported by the record. No evidence is cited for the contention that the "FTC possesses a significant advantage" due to procedural differences in merger challenges brought by the FTC and DOJ or that "few parties will want to litigate a full administrative trial." Respondents overlook their ability to choose which court of appeal will hear their appeal from an adverse decision in Part 3. Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1205. The parties to a merger challenged by DOJ are entitled to an independent factfinder—an Article III judge appointed by the President and confirmed by the Senate, with no allegiance to DOJ. 15 U.S.C. § 25. In contrast, parties to a merger challenged by the FTC in an internal administrative proceeding face an ALJ whom the FTC can replace at any time and can reverse on a de novo review, and appeal the very Commissioners who voted out the complaint and directed its prosecution. 16 C.F.R. §§ 3.42(a), 3.54.

Response to Finding No. 1205

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 242. The proposed finding is also inaccurate, irrelevant, misleading, and unsupported by the record. The contention that the FTC can replace an ALJ "at any time" contradicts Respondents' proposed finding of fact No. 1181 that "FTC ALJs may be removed only 'for good cause established and determined by' … the Merit Systems Protection Board ('MSPB'). 5 U.S.C. § 7521(a)." Respondents cite no evidence to support the suggestion that either this Court or the Commission is biased or has prejudged this matter, or that the Commission "directed the prosecution" of this matter. Respondents also overlook that adverse decisions by the Commission may be appealed to a federal court of appeal, which reviews the Commission's conclusion of law *de novo* and that its findings of fact for substantial evidence. *See Dickinson v. Zurko*, 527 U.S. 150, 162–63 (1999) (noting that the difference between the clear-error and substantial-evidence standards is "is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome").

Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents

would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1206. The parties to a merger challenged by DOJ are entitled to the protections of the Federal Rules of Civil Procedure and the Federal Rules of Evidence. *See* 15 U.S.C. § 25. Failure by DOJ to abide by the applicable procedural rules results in exclusion of evidence and potential sanctions against DOJ. *See* Fed. R. Evid. 103(d); Fed. R. Civ. P. 37. In contrast, the parties to a merger challenged by the FTC are subject to rules created by the FTC itself, do not necessarily enjoy the protections of the Federal Rules of Civil Procedure or the Federal Rules of Evidence, and must petition their accuser for relief from subpoenas and Civil Investigative Demands. 16 C.F.R. § 2.7(k). The FTC has even changed procedural rules when ALJs have ruled against it. (*See* Final Pretrial Hearing, Tr. 66 ("In fact, a lot of the rules that we abide by were – let's just say the rules were changed after I came to the Federal Trade Commission because of rulings I continually made applying Federal Rule of Evidence. That's all I'll say about that. But just remember, there's no jury. It's a bench trial.").)

Response to Finding No. 1206

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 242–43. The proposed finding is also inaccurate, irrelevant, misleading, and mischaracterizes the record. Many of the Part 3 rules are modeled from the Federal Rules. Respondents misconstrue the Court's reference to "rules [that] were changed," as the Court's statement does not support Respondents' assertion that the Commission has "changed procedural rules when ALJs have ruled against it." Respondents also ignore that they successfully petitioned the Commission, which they derisively call "their accuser," to file an action to enforce Respondents' subpoenas against a third party. *See FTC v. Caris Life Sciences*, No. 1:21mc115 (D.D.C.).

Moreover, the proposed finding is based on the incorrect assumption that an FTC

enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1207. The parties to a merger challenged by DOJ are entitled to litigate the issue in federal court alone, often in a consolidated proceeding at which the issue of preliminary and permanent injunctive relief are decided at the same time. *See* 15 U.S.C. § 25. By contrast, the parties to a merger challenged by the FTC must litigate preliminary injunctions in federal district court and permanent injunctions in an administrative proceeding subject to review by the FTC. *See* 15 U.S.C. § 53(b).

Response to Finding No. 1207

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 242–43. The proposed finding is also inaccurate, irrelevant, and misleading. It misunderstands that Congress empowered, but did not require, the FTC to seek preliminary relief in federal court under § 13(b), so not every complaint issued under § 5(b) will prompt a § 13(b) proceeding. Respondents fail to explain why, in cases where preliminary relief is sought under § 13(b), separating proceedings for federal court litigation under § 13(b) and administrative adjudication under § 5(b) could possibly make a difference to the outcome.

Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019).

Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1208. The parties to a merger challenged by DOJ face no risk that DOJ will change the district court's merits decision before appeal to the circuit court, as DOJ has no power to do so. *See Catlin v. United States*, 324 U.S. 229, 233 (1945); 28 U.S.C. § 1291. By contrast, the parties to a merger challenge in the FTC's administrative proceedings run the significant risk that the FTC will change a merits decision, including a decision that is adverse to the FTC, prior to appeal to the circuit court. 15 U.S.C. § 45(c); 16 C.F.R. § 3.54(b). The Commission is empowered to ignore an ALJ's determinations in their entirety and substitute the Commission's own legal and factual findings prior to appeal. 16 C.F.R. § 3.54. In fact, in the past 20 years, the FTC has reversed all but one decision in which this Court ruled in favor of a defendant. (RX3993 (Wright 2015) at 6); *see, e.g.*, *In re Schering-Plough Corporation*, Dkt. No. 9297 (Dec. 8, 2003); *In re Union Oil Co. of Cal.*, Dkt. No. 9305 (Jul. 6, 2004); *In re Rambus Inc.*, Dkt. No. 9302 (Jul. 31, 2006); *In re Realcomp II, Ltd.*, Dkt. No. 9320 (Oct. 30, 2009); *In re LabMD, Inc.*, Dkt. No. 9357 (Jul. 28, 2016); *In re Impax Labys, Inc.*, Dkt. No. 9373 (Mar. 28, 2019).

Response to Finding No. 1208

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of the Part 3 Rules and this Court's order on post-trial filings. *See* 16 C.F.R. § 3.46 (distinguishing between "findings of fact" and "conclusions of law"); Order on Post-Trial Filings at 1–2 (same). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." *See* Resp. Post-Trial Brief at 243.

The proposed finding is also inaccurate, vague, irrelevant, misleading, and mischaracterizes the Part 3 adjudicatory process. An FTC ALJ's initial decision is purely recommendary, as Congress gave the Commission the responsibility for making final factual findings and legal conclusions. *See* 15 U.S.C. § 45(b). Respondents ignore that, an adverse decision from a federal district court, and an adverse decision of a Commission may be appealed directly to a federal court of appeals. Respondents' assertion about reversal rates of FTC ALJs is based on unreliable hearsay, as former Commissioner Wright does not cite to the empirical data

upon which he relies to reach his conclusion. It is also vague because it neither identifies the criteria used to select the cases nor the exact time period examined. Nor can this source support Respondents' assertion relating to the outcomes of FTC decisions "in the past 26 years," since the remarks were written in 2015 and thus cannot speak to FTC decisions rendered in the last seven years. Respondents also fail to account for cases where, for example, the Commission declined to review an initial decision or dismissed counts of a complaint. *E.g. McWane v. FTC*, 783 F.3d 814, 823 n.7 (11th Cir. 2015). Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1209. The parties to a merger challenged by DOJ are entitled to factual review under the clearly erroneous standard. *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 983 (D.C. Cir. 1990) (citing Fed. R. Civ. P. 52(a)). In contrast, parties to a merger challenged by the FTC are subject to factual review under the lesser, substantial-evidence standard. *Hosp. Corp. of Am. v. F.T.C.*, 807 F.2d 1381, 1385 (7th Cir. 1986) ("Our only function is to determine whether the [FTC's] analysis of the probable effects of these acquisitions . . . is so implausible, so feebly supported by the record, that it flunks even the deferential test of substantial evidence.").

Response to Finding No. 1209

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rule." (*See* Rule 3.46; Order on Post-Trial Findings). Respondents have merely recited a portion of their own Post-Trial Brief – in effect representing their argument as a "fact." (*See* Resp.'s Post-Trial Brief at 243). The proposed finding is also inaccurate, irrelevant, and misleading. In mistakenly asserting that the substantial evidence standard is "lesser," Respondents misunderstand that legal conclusions by either the Commission or by a federal district court are reviewed *de novo* by the

courts of appeal, and any difference between the standards for reviewing factual findings "is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome." *Dickinson v. Zurko*, 527 U.S. 150, 162–63 (1999). Respondents cite no case where the difference in appellate standards for reviewing factual findings was outcome-determinative. Moreover, the proposed finding is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). Any differences in adjudicatory procedures or their outcomes are irrelevant, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

1210. The choice of whether a challenge is brought by DOJ or the FTC is sorted out by the agencies themselves through an informal, non-public, unwritten process called "clearance". (RX4012 (Muris 2005) at 4.)

Response to Finding No. 1210

The proposed finding is misleading and irrelevant, as it is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). The allocation of matters between DOJ and the FTC is irrelevant because Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel. In any event, the agencies' allocation arrangement serves the legitimate governmental purpose of conserving government resources by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. Therefore, this Court should disregard the proposed finding.

1211. At times, the FTC and DOJ have decided which agency will handle a case by a coin flip. (RX4011 (Koenig 2020) at 1.)

Response to Finding No. 1211

The proposed finding is misleading and irrelevant, as it is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). The allocation of matters between DOJ and the FTC is irrelevant because Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel. Respondents cite no evidence that the allocation of their own matter was "decided … by a coin flip." In any event, the agencies' allocation arrangement serves the legitimate governmental purpose of conserving government resources by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. Therefore, this Court should disregard the proposed finding.

1212. Even when the choice of reviewing agency is not the product of a coin toss, the clearance process is "opaque at best", often resulting in clearance disputes rather than an allocation based on reason. (RX4012 (Muris 2005) at 4.)

Response to Finding No. 1212

The proposed finding is misleading and irrelevant, as it is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). The allocation of matters between DOJ and the FTC is irrelevant because Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel. Respondents cite no evidence that the allocation of their own matter resulted in a "dispute" that was not "based on

reason." In any event, the agencies' allocation arrangement serves the legitimate governmental purpose of conserving government resources by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. Therefore, this Court should disregard the proposed finding.

1213. Former director of the FTC's Bureau of Competition from 2013 to 2017 has stated that "every deal [she had] worked on [had] been mired in a clearance dispute between the agencies . . even for industries . . . she would have thought would clearly fall into one agency's particular expertise". (RX4011 (Koenig 2020) at 1–2.)

Response to Finding No. 1213

The proposed finding is misleading and irrelevant, as it is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). The allocation of matters between DOJ and the FTC is irrelevant because Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel. Respondents cite no evidence that the allocation of their own matter was "mired in a clearance dispute." In any event, the agencies' allocation arrangement serves the legitimate governmental purpose of conserving government resources by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. Therefore, this Court should disregard the proposed finding.

1214. While a 2002 Clearance Agreement reformed the clearance process and sought to capitalize on each agency's "industry-specific knowledge", allocating merging parties based on past industry-specific knowledge is no less arbitrary. (RX4012 (Muris 2005) at 9, 11.)

Response to Finding No. 1214

The proposed finding is misleading and irrelevant, as it is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually

exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). The allocation of matters between DOJ and the FTC is irrelevant because Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel. Respondents cite no evidence that the allocation of their own matter was "arbitrary." In any event, the agencies' allocation arrangement serves the legitimate governmental purpose of conserving government resources by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. Therefore, this Court should disregard the proposed finding.

1215. Which agency has expertise in a particular industry is an accident of history. (*See* RX4012 (Muris 2005) at 9) ("[T]he new [2002 clearance] agreement recognized historical patterns of enforcement activity and expertise.").)

Response to Finding No. 1215

The proposed finding is misleading and irrelevant, as it is based on the incorrect assumption that an FTC enforcement action and a DOJ enforcement action are mutually exclusive. *See In re Otto Bock HealthCare North America, Inc.*, No. 9378, 2019 WL 5957363, at *51 (F.T.C. Nov. 1, 2019). The allocation of matters between DOJ and the FTC is irrelevant because Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel. Respondents cite no evidence that the allocation of their own matter was the result of "an accident of history." In any event, the agencies' allocation arrangement serves the legitimate governmental purpose of conserving government resources by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. Therefore, this Court should disregard the proposed finding.

X. TESTIMONIAL EVIDENCE

A. Illumina

1. Francis deSouza

a. Background

1216. Francis deSouza is the CEO of Illumina and has served in that role since July 2016. (deSouza (Illumina) Tr. 2306.) Mr. deSouza's responsibilities include setting the long-term strategy and vision for Illumina, managing the operations of Illumina and overseeing building of products and various teams such as the commercial, regulatory affairs, market access, clinical affairs, finance, human resources and legal teams. (deSouza (Illumina) Tr. 2306, 2309.)

Response to Finding No. 1216

The proposed finding is misleading to the extent that it implies Mr. deSouza has the foundation to testify regarding the details of Illumina's "overseeing and building of products" or the day-to-day operations and/or details of the "commercial, regulatory affairs, market access, clinical affairs, finance, human resources and legal teams." *See e.g.,* (PX7107 deSouza (Illumina) Dep. at 18-19; 28; 79)). Therefore, this Court should disregard the proposed finding.

1217. Mr. deSouza joined Illumina in 2013 as President of the company and he was responsible for running Illumina's product development, engineering, manufacturing, and quality teams. (deSouza (Illumina) Tr. 2308–09.) Mr. deSouza's role as President involved overseeing Illumina's entire portfolio of products, including Illumina's sequencers, library preparation kits, IVD cystic fibrosis assay and software products. (deSouza (Illumina) Tr. 2309.) Mr. deSouza was President of Illumina at the time that GRAIL was created and spun off and CEO of Illumina at the time that Illumina decided to reacquire GRAIL. (deSouza (Illumina) Tr. 2308–09, 2194–95.)

Response to Finding No. 1217

Complaint Counsel has no specific response to the proposed finding.

1218. Mr. deSouza has a bachelor's degree in electrical engineering and a master's degree in electrical engineering and computer science, both from the Massachusetts Institute of Technology (MIT). (deSouza (Illumina) Tr. 2307.)

Response to Finding No. 1218

Complaint Counsel has no specific response to the proposed finding.

b. Testimony

1219. The Transaction. Mr. deSouza testified that: Illumina decided to acquire GRAIL because Illumina believed it could dramatically accelerate the availability of Galleri around the world and dramatically improve the accessibility of Galleri to people around the world, which not only benefits the public writ large, but also aligned with Illumina's mission and allowed Illumina to create significant value for Illumina's shareholders, (deSouza (Illumina) Tr. 2334–35); the impact of the Transaction is the potential to "fundamentally dent the mortality curve related to cancer and save many, many thousands of lives around the world" by Illumina accelerating access in the United States and across the globe to the life-saving Galleri test through leveraging Illumina's broad experience and capabilities, (deSouza (Illumina) Tr. 2411–12).

Response to Finding No. 1219

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's bias makes this finding inherently unreliable. The proposed finding is also incorrect and against the weight of the evidence that shows Respondents have failed to satisfy their burden to show that the purported "acceleration" of the Galleri test is a cognizable efficiency. [redacted] The proposed finding is also misleading to the extent it implies that Illumina was not motivated by the large projected profits of the MCED market. [redacted] As, Mr. deSouza told investors at the Cowen Liquid Biopsy Summit, Illumina did a financial analysis as part of the deal and "moving from selling platforms to Grail and participating in the revenue stream to owning Grail" is "significantly value-accretive to Illumina shareholders." (deSouza, Tr. 2219-20; PX2575 at 059-60, 80 (Illumina M&A Call, Sept. 21, 2020)).

Given that the proposed finding is based solely on Mr. deSouza's biased, unsubstantiated testimony and controverted by the weight of the evidence, the proposed fact should be disregarded in its entirety.

1220. Efficiencies. Mr. deSouza testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies, the elimination of double marginalization, the elimination of the royalty GRAIL owes to Illumina, supply chain and operational efficiencies, and accelerating international availability of Galleri. (deSouza (Illumina) Tr. 2342–78.) Despite Complaint Counsel's attempts to impeach Mr. deSouza with his IH testimony in an attempt to undermine his trial testimony on efficiencies, Mr. deSouza emphasized the IH testimony used by Complaint Counsel was taken out of context and does not in any way change his conviction that the Transaction will result in significant efficiencies. (deSouza, Tr. 2426–27.)

Response to Finding No. 1220

[redacted]

[redacted]

1221. *Saving Lives.* Mr. deSouza testified that by accelerating access to Galleri the Transaction has the potential to "fundamentally dent the mortality curve in cancer" and save over 10,000 lives in the U.S. alone over the next nine years. (deSouza (Illumina) Tr. 2411–12.)

Response to Finding No. 1221

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's bias makes this finding inherently unreliable. The weight of the evidence instead shows that Respondents have failed to adduce evidence sufficient to substantiate Respondents' claim that Illumina's acquisition of Grail will accelerate adoption of Grail is a cognizable efficiency that will result from this transaction. [redacted] The proposed finding should be disregarded given it is supported only by the biased testimony of an Illumina executive and controverted by the overwhelming weight of the evidence.

1222. Mr. deSouza explained that Illumina will make Galleri more accessible globally, more quickly than GRAIL and that GRAIL only plans to launch its product in the U.S., UK and Canada but Illumina will expand the test to other less wealthy countries, such as India and countries in Africa. (deSouza (Illumina) Tr. 2412–13.)

Response to Finding No. 1222

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's bias makes this finding inherently unreliable. The proposed finding is also irrelevant given out-of-market efficiencies cannot be cognizable and should be disregarded on that basis alone. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Mr. deSouza also does not have the foundation to testify as to Illumina's comparative ability to bring the Galleri test to international markets. [redacted] Mr. deSouza also does not have knowledge of Grail's employee expertise. (deSouza (Illumina) Tr. 2419). As such, Mr. deSouza has limited knowledge of Grail's abilities. The proposed finding is also unsupported given it is supported only by the biased testimony of an Illumina executive and controverted by the overwhelming weight of the evidence that shows Illumina has failed to meet its burden to provide cognizable, merger-specific efficiencies [redacted] Therefore, this Court should disregard the proposed finding.

1223. *Accelerating Market Access to Galleri*. Mr. deSouza testified that FDA approval allows for an MCED test to be run in hospital and healthcare systems in addition to a GRAIL central laboratory thereby increasing patient access to the test, (deSouza (Illumina) Tr. 2346); CMS approval broadens access of Galleri to communities that are traditionally underserved by the healthcare system and payer approval will be absolutely critical in the adoption of Galleri, (deSouza (Illumina) Tr. 2346–47, 2350).

Response to Finding No. 1223

The proposed testimony is unsupported, misleading, and against the weight of the

evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's bias makes this finding inherently unreliable. Mr. deSouza also does not have the foundation to testify about the implications of CMS approval given Illumina's minimal experience in obtaining CMS approval or payer coverage. [redacted] Moreover, the proposed finding is misleading to the extent it implies that Illumina will be able to accelerate Galleri's FDA and CMS approval. As explained in Complaint Counsel's Post-Trial Reply Brief, Respondents have failed to meet their burden to show cognizable efficiencies, including that this merger will accelerate FDA and CMS approval of Galleri. (Complaint Counsel's Post-Trial Reply Brief at Section V.); [redacted] Given that this proposed finding is only supported by the biased, unqualified testimony of Mr. deSouza, it should be disregarded.

1224. Mr. deSouza explained that Galleri currently costs $950, which is a price many Americans cannot afford and makes payer coverage and reimbursement of Galleri absolutely critical to enabling widespread adoption and availability. (deSouza (Illumina) Tr. 2350–51.)

Response to Finding No. 1224

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's bias makes this finding inherently unreliable. Moreover, the Board of Directors will consider whether this

acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza does not have the foundation to testify about the implications of CMS approval given Illumina's minimal experience in obtaining CMS approval or payer coverage. [redacted] Moreover, the proposed finding is misleading to the extent it implies that Illumina will be able to accelerate Galleri's FDA and CMS approval. As explained in Complaint Counsel's Post-Trial Reply Brief, Respondents have failed to meet their burden to show cognizable efficiencies, including that this merger will accelerate FDA and CMS approval of Galleri. (Complaint Counsel's Post-Trial Reply Brief at Section V.; [redacted] Given that this proposed finding is only supported by the biased, unqualified testimony of Mr. deSouza it should be disregarded.

1225. Mr. deSouza provided testimony about Illumina's experience in obtaining FDA and CMS approval of products that it can leverage to accelerate FDA and CMS approval of Galleri, including that: Illumina has nearly a decade of experience working with the FDA and CMS on obtain approval for products, (deSouza (Illumina) Tr. 2347); the FDA's clearance in 2013 of Illumina's MiSeqDx next generation sequencer as an open platform next generation sequencer was the first such approval by the FDA, (deSouza (Illumina) Tr. 2344, 2347); Illumina has also obtained FDA approval of its NextSeqDx sequencer and is working on obtaining approval of its NovaSeq sequencer, (deSouza (Illumina) Tr. 2348); Michigan became the first state in the United States in which Medicaid covers rapid whole genome sequencing for critically ill children in the NICU and that breakthrough is due to work that Illumina has done over the past few years, (deSouza (Illumina) Tr. 2342); in 2013, Illumina's cystic fibrosis test was the first NGS-based test cleared by the FDA, (deSouza (Illumina) Tr. 2344); and partly because of Illumina's risk-sharing agreements with insurance companies, insurance coverage for NIPT has gone from being nearly nonexistent to covering over 190 million people, (deSouza (Illumina) Tr. 2343).

Response to Finding No. 1225

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of

Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's biased testimony regarding Illumina's alleged experience with the FDA is irrelevant. [redacted] Moreover, Mr. deSouza said that each FDA submission is "very specific to your test in terms of the claim." (PX7072 deSouza (Illumina) IHT at 195). Mr. deSouza's own testimony illustrates that Illumina does not have any unique experiences that will be useful in accelerating FDA or CMS approval of the Galleri test. Likewise, Illumina's alleged experience in genomics and NIPT is also irrelevant to their ability to accelerate payer acceptance for the Galleri test, as explained Complaint Counsel's Post-Trial Reply Brief. *See* (Complaint Counsel's Post-Trial Reply Brief at Section V.B.). The weight of the evidence instead shows that Respondents have failed their burden to show that this transaction will be able to accelerate Galleri's FDA and CMS approval. [redacted] Therefore, this Court should disregard the proposed finding.

1226. Mr. deSouza explained that Illumina can accelerate payer coverage and reimbursement of Galleri because: Illumina has nearly a decade of experience working with payers to obtain approval of genomic tests and will utilize its experience and relationships for approval of Galleri, (deSouza (Illumina) Tr. 2351–53); Illumina has helped one billion people around the world obtain payer reimbursement for genomic tests and has deep expertise, innovative tools and deep relationship that it can utilize to accelerate payer coverage of Galleri; (deSouza (Illumina) Tr. 2342–43); and Illumina's experience with entering into risk-sharing agreements with insurance companies enables Illumina to work effectively with insurance companies on building the data necessary for insurance companies to cover a test, (deSouza (Illumina) Tr. 2343).

Response to Finding No. 1226

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream

market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's testimony is not credible. Aside from being biased, he provided no details explaining how much Illumina allegedly helped people obtain reimbursement for genomics tests or how that experience is transferable to accelerating payer acceptance for an MCED test. Moreover, Mr. deSouza's testimony is controverted by documents and testimony of other witnesses that explain that Illumina's tiny market access shop of 13 – only two of which are focused on US-payer relationships – does not have sufficient expertise to meaningfully accelerate payer adaption. (Qadan (Illumina) Tr. 4289; 4292). [redacted] Therefore, this Court should disregard the proposed finding.

1227. Mr. deSouza testified that in comparison to Illumina, GRAIL has a tiny team dedicated to FDA and CMS approval, (deSouza (Illumina) Tr. 2348); and the GRAIL team focused on payer approval has only nascent experience, (deSouza (Illumina) Tr. 2352).

Response to Finding No. 1227

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's testimony is not credible. Mr. deSouza also does not have the foundation to testify about Grail's capabilities given that he is unfamiliar with the expertise of the Grail team. (deSouza, Tr. at 2419). Further, the

overwhelming weight of the evidence shows that Grail had a well-thought out and well-resourced plan to get payer acceptance for the Galleri test. [redacted] As explained in Complaint Counsel's Post-Trial Reply Brief, Respondents have failed to meet their burden to show that Illumina's ability to accelerate payer acceptance is a merger-specific, verifiable efficiency of this transaction. (Complaint Counsel's Post-Trial Reply Brief at Section V.B.; [redacted]. Therefore, this Court should disregard the proposed finding.

1228. Mr. deSouza explained that after consummation of the merger, Illumina plans to quickly start the large-scale evidence generation and initiation of studies required to obtain FDA, CMS and payer approval for Galleri, (deSouza (Illumina) Tr. 2349–50); and that Illumina plans to leverage its existing models from its experience in obtaining payer approval of prior products (in NIPT, genetic disease diagnosis and cancer therapy selection) to help accelerate payer approval of Galleri (deSouza (Illumina) Tr. 2349).

Response to Finding No. 1228

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's testimony is not credible. Aside from being biased it is also irrelevant. He fails to articulate how Illumina's alleged experience in non-MCED markets will be transferable. Instead, as the evidence shows, Illumina's alleged experience in NIPT, genetic disease diagnosis and cancer therapy selection (aside from being overstated) is also not relevant to accelerating payer reimbursement for Galleri. [redacted] Moreover, as Complaint Counsel's expert explains (and Respondents ordinary course documents show) Grail has a well-thought out and well-resourced

plan to gain payer acceptance for the Galleri test. [redacted] Moreover, the weight of the evidence shows that Illumina has failed to substantiate that its alleged ability to accelerate payer acceptances is a merger-specific, verifiable efficiency of this transaction. [redacted] Therefore, this Court should disregard the proposed finding.

1229. *Research and Development Efficiencies*. Mr. deSouza testified about Illumina's commitment to research and development to expand market opportunities for Illumina's business, including that research and development is absolutely critical to Illumina because innovation will unlock the future markets for genomics, (deSouza (Illumina) Tr. 2353); in 2020, Illumina invested $600 million in research and development, (deSouza (Illumina) Tr. 2354); Illumina has focused on driving the cost of sequencing down because the lower the prices are to consumers, the more opportunities to utilize sequencing for products opens up, (deSouza (Illumina) Tr. 2353); and innovation will allow for genomic tests to be easier for patients and physicians to understand and Illumina is focused on innovating to create simplicity that will grow the genomics market, (deSouza (Illumina) Tr. 2353–54).

Response to Finding No. 1229

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's testimony is not credible. His testimony is also irrelevant. [redacted] Instead, as the weight of the evidence shows, Respondents will have the ability and incentive to disadvantage Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding.

1230. Mr. deSouza testified that the Transaction will create research and development efficiencies, for example: Illumina has over a decade of experience in optimizing workflows for the processing of genomic tests and will utilize that experience to optimize the workflow for Galleri, and optimizing the Galleri workflow will allow an increased number of tests to be run in a production environment and eliminate waste, which will result in lowering the cost per test for Galleri, (deSouza (Illumina) Tr. 2356–58); and the Illumina and GRAIL teams can work together on research and development of new genomic tests by, among other things, seeking to identify genomic biomarkers in the blood for conditions such as fatty liver disease, Alzheimer's Disease and Parkinson's Disease, (deSouza (Illumina) Tr. 2356).

Response to Finding No. 1230

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's testimony actually proves that the ability to optimize workflows is not a merger-specific efficiency, eliminating this efficiency as a cognizable merger-specific efficiency. (deSouza (Illumina) Tr. at 2426). Mr. deSouza's testimony regarding Illumina's alleged research and development capabilities is also irrelevant given that those are impermissible out-of-market efficiencies. (Complaint Counsel's Post-Trial Reply Brief at Section V.C.). Mr. deSouza also admitted that these alleged research and development efficiencies are speculative. Specifically, Mr. deSouza testified on cross-examination that Illumina had not formed any teams to research these diseases and that it's impossible to know today "what the outcome may be." (deSouza (Illumina), Tr. 2423-24). Further, Mr. deSouza's testimony is against the weight of the evidence which shows that Illumina has failed to meet its burden to show that research and development would be a cognizable efficiency resulting from this merger. (Complaint Counsel's Post-Trial Reply Brief at

Section V.C.); [redacted] Therefore, this Court should disregard the proposed finding.

1231. Mr. deSouza explained that absent the merger, GRAIL's team would be unable to focus on developing new genomic tests because their team is fully focused on scaling Galleri, GRAIL's diagnostic cancer test and GRAIL's MRD test and will not have the time and resources needed to develop new genomic tests. (deSouza (Illumina) Tr. 2357.)

Response to Finding No. 1231

[redacted]

[redacted]

1232. *Elimination of Royalties*. Mr. deSouza testified that the Transaction will generate cost saving synergies, including that: before the Transaction, GRAIL owed Illumina a royalty and after the close the Transaction, GRAIL no longer owes that royalty. (deSouza (Illumina) Tr. 2358.)

Response to Finding No. 1232

[redacted]

[redacted]

1233. *Elimination of Double Marginalization*. Mr. deSouza testified that Illumina charged a margin to GRAIL on next generation sequencing products prior to the Transaction and GRAIL projected that margin into the future, but the Transaction will eliminate double marginalization. (deSouza (Illumina) Tr. 2359–60.)

Response to Finding No. 1233

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). [redacted] Accordingly,

Mr. deSouza's made-for-litigation testimony should be disregarded given his bias and lack of foundation. Moreover, the weight of the evidence shows that Respondents have not met their burden to show that elimination of double-marginalization is a verifiable, merger-specific efficiency that will result from this merger. [redacted]

1234. *Supply Chain and Operational Efficiencies*. Mr. deSouza testified to the supply chain and operational efficiencies the Transaction will create, including that: compared to GRAIL, Illumina is a much larger purchaser of materials needed for Galleri and will be able to deeper discounts for those materials, which will lower the cost of Galleri, (deSouza (Illumina) Tr. 2345); Illumina is a large purchaser of raw materials, and consolidating the quantity of raw materials that Illumina purchases with the quantity of raw materials that GRAIL purchases will generate even larger discounts for Illumina, which discounts are already larger than GRAIL's, and the discounts will result in a lower price to consumers for Galleri, (deSouza (Illumina) Tr. 2369–70); and Illumina has deeper experience than GRAIL in relation to purchasing raw materials and will be better able to identify suppliers that provide superior cost performance of inputs for the Galleri test, which will result in a lower price to consumers for Galleri, (deSouza (Illumina) Tr. 2369–70).

Response to Finding No. 1234

[redacted]

[redacted]

1235. Mr. deSouza testified to the lab operation efficiencies the Transaction will create, including that: Illumina already has high-throughput genomic testing laboratories in operation and can leverage its facilities, equipment and personnel to ramp up production of Galleri, (deSouza (Illumina) Tr. 2341); GRAIL runs Galleri out its development laboratory in Menlo Park, California, but Illumina has production laboratories in the United States and abroad that are able to run millions of tests and accelerate scaling Galleri, (deSouza (Illumina) Tr. 2370–71); a "certain level of sophistication" is required to run genomic testing pipeline, and Illumina already has the facilities, equipment and personnel needed to bring Galleri to scale, (deSouza (Illumina) Tr. 2371); Illumina has developed custom automation tools to run highly automated laboratories and software pipelines to analyze data from samples in a high throughput manner, (deSouza (Illumina) Tr. 2371–72); and it would take years for GRAIL to develop operational capabilities similar to the capabilities Illumina has and that GRAIL will be able to take advantage of as a result of the Transaction, (deSouza (Illumina) Tr. 2372).

Response to Finding No. 1235

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's biased, testimony is incorrect.

[redacted] Moreover, as explained in Complaint Counsel's Reply Brief, Illumina has failed to meet their burden to show that lab operation efficiencies are a cognizable benefit of this merger. (Complaint Counsel's Post-Trial Reply Brief at Section V.F.); [redacted] Therefore, this Court should disregard the proposed finding.

1236. *Expanding International Availability*. Mr. deSouza testified to facts regarding Illumina's ability to accelerate international availability of the Galleri, including that: Illumina has a strong international presence and more than half of Illumina's revenue is generated in countries other than the United States, (deSouza (Illumina) Tr. 2374); Illumina has placed products in over 140 countries around the world and has obtained clearance of products in dozens of countries, which creates a connection between Illumina and the medical communities and regulatory bodies in the countries in which Illumina operates, (deSouza (Illumina) Tr. 2374); and Illumina's presence and experience internationally allows Illumina to be able to identify and respond to customer issues quickly, (deSouza (Illumina) Tr. 2374).

Response to Finding No. 1236

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Respondents have provided no documents or any details at all to corroborate Mr. deSouza's biased testimony, as such this proposed finding should be disregarded. Mr. deSouza's testimony is also irrelevant. As Complaint Counsel's Post-Trial Reply Brief explains, out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Moreover, the weight of the evidence shows that

Respondents have failed to meet their burden to show that international availability is a merger-specific, cognizable efficiency. [redacted] Therefore, this Court should disregard the proposed finding.

1237. Mr. deSouza explained that GRAIL only recently hired someone in the United Kingdom and does not have a presence in any countries around the world other than the United Kingdom and United States, (deSouza (Illumina) Tr. 2374–75); and absent the merger, GRAIL's plan is to make Galleri available only in the United States, Canada and the United Kingdom in the next five years, (deSouza (Illumina) Tr. 2375).

Response to Finding No. 1237

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Respondents have provided no documents to corroborate Mr. deSouza's biased testimony, as such this proposed finding should be disregarded. Mr. deSouza's testimony is also irrelevant. As Complaint Counsel's Post-Trial Reply Brief explains, out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Moreover, the weight of the evidence shows that Respondents have failed to meet their burden to show that international acceleration is a cognizable efficiency. [redacted] Therefore, this Court should disregard the proposed finding.

1238. Mr. deSouza pointed out that on its own, GRAIL will not get the test to countries such as Africa and India even over the next decade; that Illumina feels a sense of urgency to get the test on the market and that Illumina will make Galleri available globally and more accessible globally than GRAIL would on its own. (deSouza (Illumina) Tr. 2412–13.)

Response to Finding No. 1238

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Respondents have provided no documents to corroborate Mr. deSouza's biased testimony, as such this proposed finding should be disregarded. Mr. deSouza's testimony is also irrelevant. As Complaint Counsel's Post-Trial Reply Brief explains, out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Moreover, the weight of the evidence shows that Respondents have failed to meet their burden to show that international acceleration is a cognizable efficiency. [redacted] Therefore, this Court should disregard the proposed finding.

1239. Mr. deSouza noted that Galleri being available around the world will improve the test because the algorithms get more refined and the test become more accurate based on more tests being run and analyzing diverse samples, (deSouza (Illumina) Tr. 2373); and cancer is a global disease and expanding availability around the globe faster will result in additional saved lives, (deSouza (Illumina) Tr. 2372–73).

Response to Finding No. 1239

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). Moreover, the Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Respondents have provided no documents to

corroborate Mr. deSouza's biased testimony, as such this proposed finding should be disregarded. Mr. deSouza's testimony is also irrelevant. As Complaint Counsel's Post-Trial Reply Brief explains, out-of-market efficiencies are not cognizable. (Complaint Counsel's Post-Trial Reply Brief at Section V.). Moreover, the weight of the evidence shows that Respondents have failed to meet their burden to show that international acceleration is a cognizable efficiency. [redacted] Therefore, this Court should disregard the proposed finding.

1240. For the efficiencies Mr. deSouza testified to, he explained that GRAIL would not be able to achieve those efficiencies absent the merger because: no other company or consulting firm can match Illumina's expertise in market access, clinical affairs, commercialization, regulatory approval and international expansion for genomics tests; customers are unwilling to share proprietary information with Illumina; and Illumina is not set up to be a consulting firm that makes its expertise available on fee basis. (deSouza (Illumina) Tr. 2377–78.)

Response to Finding No. 1240

[redacted]

[redacted]

1241. [redacted]

Response to Finding No. 1241

[redacted]

[redacted]

[redacted]

[redacted]

1242. *Raising GRAIL Rivals' Costs*. Mr. deSouza explained that: Illumina's core business is to sell sequencers and consumables to customers that include government institutions, researchers, academic medical centers, hospitals and healthcare systems, laboratories and private companies that provide genetic tests, (deSouza (Illumina) Tr. 2313–14, 2378); Illumina's customers use Illumina's products for a wide range of applications, (deSouza (Illumina) Tr. 2322–23); even in areas where Illumina provides a competing test, such as NIPT and cancer therapy selection, Illumina earns significantly more revenue by selling sequencers and consumables than it does selling tests, (deSouza (Illumina) Tr. 2378–79); [redacted]

Response to Finding No. 1242

[redacted]

[redacted]

1243. Mr. deSouza testified that: Illumina does not have any incentive to raise prices to any GRAIL rival or potential GRAIL rival because that would jeopardize Illumina's core business of selling sequencers and consumables, (deSouza (Illumina) Tr. 2378–79, 2387–88); if Illumina raised prices to GRAIL's rivals or potential rivals, the companies would switch to another platform such as those provided by Thermo Fisher or BGI, (deSouza (Illumina) Tr. 2379–80); and companies performing genomic analysis have a number of choices and can decide to use short-read sequencers, long-read sequencers, microarrays or PCR platforms. (deSouza (Illumina) Tr. 2323–26.)

Response to Finding No. 1243

[redacted]

[redacted]

[redacted]

1244. Mr. deSouza noted that Illumina's revenue from selling sequencers and consumables to companies who provide cancer therapy selection tests is fourteen times higher than Illumina's revenue from selling its own cancer therapy selection test, (deSouza (Illumina) Tr. 2379); and Illumina's revenue from selling sequencers and consumables to companies who provide NIPTs is eight times higher than Illumina's revenue for selling its own NIPT, (deSouza (Illumina) Tr. 2379).

Response to Finding No. 1244

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 (deSouza IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 (deSouza IHT at 259). Mr. deSouza's self-serving testimony is unsupported by any documents and should be disregarded on that basis alone. Mr. deSouza's testimony is also irrelevant. Illumina's comparative revenue in the NIPT or therapy selection market is irrelevant as to whether Illumina has the ability or incentive to foreclose in the MCED market. As Mr. deSouza told investors, "I'd like to point out that the Grail acquisition gives us a leading position in this very large market opportunity. And the early detection of cancer market dwarfs the clinical markets we see today,

NIPT, and therapy selection for oncology combined." (deSouza, Tr. 2216-18; PX2575 at 059-60 (Illumina M&A Call, Sept. 21, 2020)). Mr. deSouza went on to say, "by participating directly in that segment with our own solution, it allows us as Illumina to get a larger percentage of the value created in that solution rather than just being the platform provider." (deSouza, Tr. 2216-18; PX2575 at 059-60 (Illumina M&A Call, Sept. 21, 2020)). The proposed finding is controverted by the clear weight of the evidence that shows Illumina has the ability and incentive to disadvantage Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding.

1245. Mr. deSouza explained that the projected size of the profit pool for MCED tests does not provide Illumina with an incentive to favor GRAIL over GRAIL's rivals or potential rivals because: Illumina is not projected to earn a profit on the GRAIL transaction until after 2030, which means Illumina must continue to rely on its sequencing sales to drive profitability, (deSouza (Illumina) Tr. 2382–83); and the profitability margin for testing is not projected to be larger than the profitability margin for sequencing sales, (deSouza (Illumina) Tr. 2385–86).

Response to Finding No. 1245

[redacted]

1246. *Small Cost of Sequencing Inputs.* Mr. deSouza testified to facts showing that Illumina raising the costs of sequencing would be ineffective due to the small percentage of sequencing costs in the overall cost of an MCED test, because: in 2007, the cost to sequence a human genome cost approximately $150,000 and currently the cost to sequence a human genome on Illumina's NovaSeq is $600, representing an over 99% reduction in the price of sequencing over that time span, (deSouza (Illumina) Tr. 2327–28); Illumina has driven down the cost of sequencing by focusing on research and development as well as technology innovation that drive down costs, and lower sequencing costs has, among other things, vastly expanded the number of applications that use sequencing technologies and made clinical tests affordable to a broader population, (deSouza (Illumina) Tr. 2328–29); Illumina plans to reduce the cost of sequencing further by increasing the density of its flow cells, reducing the wavelength of the light in the optical assembly, speeding up the platform's chemistry and accelerating it algorithms and data

paths, which Illumina is doing to reach a point where it can provide a solution that sequences a genome for one hundred dollars, (deSouza (Illumina) Tr. 2330–31, 2397–98); and sequencing costs today represent about ten percent of the price of Galleri and Illumina projects the percentage to be less than four percent by 2025, (deSouza (Illumina) Tr. 2388).

Response to Finding No. 1246

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza IHT at 259). Mr. deSouza's self-serving testimony is unsupported by any documents and should be disregarded on that basis alone. Further, Mr. deSouza's testimony is irrelevant. Whether or not Illumina is lowering price or innovating is irrelevant as to whether Respondents have the ability or incentive to foreclose Grail's rivals. As Dr. Katz explained, even monopolists may have incentive to innovate or reduce price. (PX7145 Katz (Illumina) Dep. at 70). Instead, as the evidence shows, Illumina will have the ability and incentive foreclose Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding.

1247. *Not Cooperating With GRAIL Rivals*. Mr. deSouza provided testimony about Illumina's business strategy to expand the use of its products by cooperating with test providers, including that: Illumina's ethos and strategy has always been to be an open systems platform to allow customers to not only use Illumina's suite of products, but also to use other companies' sequencing products for one part of the sequencing workflow and Illumina's products in another, ([redacted]); and Illumina wants to expand the market for NGS-based testing and cooperating with potential GRAIL rivals expands the market for selling sequencers and consumables, (deSouza (Illumina) Tr. 2390).

Response to Finding No. 1247

[redacted]

[redacted]

1248. Mr. deSouza noted that: Illumina does not have any history of foreclosing potential competition after acquiring a testing company, (deSouza (Illumina) Tr. 2393–94); following Illumina's acquisition of Verinata (an NIPT provider) in 2013, Illumina did not take any steps to foreclose Natera with respect to the provision of NIPTs, (deSouza (Illumina) Tr. 2393); and while the number of NIPTs ordered has increased since 2013, Illumina's share of NIPT sales have decreased since 2013, (deSouza (Illumina) Tr. 2393–94).

Response to Finding No. 1248

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue

and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259).

Mr. deSouza's self-serving testimony is unsupported by the evidence. [redacted] Therefore, this Court should disregard the proposed finding.

1249. Mr. deSouza testified that Illumina does not have an incentive to not cooperate with any potential GRAIL rival because: Illumina's open platform ethos and strategy allows customer to switch to another sequencer, but continue to use the same data management platform and library preparation kits, (deSouza (Illumina) Tr. 2386–87); customers who observe Illumina's foreclosure conduct, regardless of whether that customer provides an MCED test or not, will cease doing business with Illumina, (deSouza (Illumina) Tr. 2380–82, 2387–88); if Illumina did not cooperate with a potential GRAIL rival to advantage GRAIL, it would have ripple effects across Illumina's customer base and negatively affect Illumina's core sequencing business, (deSouza (Illumina) Tr. 2390); and Illumina's current contracts with customers prevent Illumina from failing to cooperate with customers because Illumina is required to provide support services under the contracts, (deSouza (Illumina) Tr. 2391).

Response to Finding No. 1249

[redacted]

[redacted]

[redacted]

1250. *Inability To Capture Diverted Sales.* Mr. deSouza explained that Illumina would not be able to make up for sales it lost from engaging in foreclosure activities because: Galleri and other MCED tests will not be substitutes for one another, (deSouza (Illumina) Tr. 2380–82, 2387–88); Illumina employees and Mr. deSouza talked to a number of doctors who informed Illumina that a fifty-cancer test like Galleri will serve different needs than tests that screen for one cancer type or ten or fewer cancer types and that a cancer screening test that detects cancer signal of origin will not compete with a cancer screening test that does not detect cancer signal of origin, (deSouza (Illumina) Tr. 2336–37); and a customer is likely to switch to a non-NGS-based test as opposed to another NGS-based test, (deSouza (Illumina) Tr. 2380–82).

Response to Finding No. 1250

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's testimony should be discounted on that alone. Mr. deSouza's testimony is based on the out-of-court statements of "doctors" with whom he allegedly spoke. Without more context regarding the qualifications of these "doctors", an understanding of their knowledge regarding different MCED tests, as well as the exact questions posed, these statements have no probative value. These out-of-court statements are inherently unreliable hearsay providing yet another reason why Mr. deSouza's testimony should be disregarded. Mr. deSouza both overstates Galleri's capabilities and understates the capabilities

of Grail's rivals. [redacted] Therefore, this Court should disregard the proposed finding.

1251. *Investment Activity*. Mr. deSouza testified to facts showing that investment activity reflects a lack of investor concern of Illumina foreclosing competition after consummation of the transaction, including that: after the announcement of the merger, investment in the MCED market significantly ramped up, (deSouza (Illumina) Tr. 2392); following the announcement of the Illumina-GRAIL transaction Exact acquired Thrive, which had no commercially available product and no revenue, (deSouza (Illumina) Tr. 2392); and in the past, Illumina has seen similarly increased investments in potential rival NIPT companies after acquiring Verinata, (deSouza (Illumina) Tr. 2392–93).

Response to Finding No. 1251

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). Mr. deSouza's testimony also lacks foundation to speak to whether investment has increased as well as the implications for that increase. Mr. deSouza is not one of the investors to which he is referring nor is he an expert who is qualified to opine on

the implications of that investment. [redacted]. Moreover, Illumina's alleged increased investment in potential rival NIPT companies after acquiring Verinata is both unsubstantiated as well as irrelevant. Finally, the weight of the evidence actually shows that any entry of NGS alternatives will not be timely, likely, or sufficient. (CCFF § VIII(B)). Therefore, this Court should disregard the proposed finding.

1252. Open Offer. Mr. deSouza provided testimony about Illumina's Open Offer and explained that: Illumina drafted the Open Offer to resolve the objections to the Transaction raised by Complaint Counsel and customers, (deSouza (Illumina) Tr. 2338, 2401); following the announcement of the Transaction, Illumina reached out to customers to quell concerns about the Transaction, (deSouza (Illumina) Tr. 2290); certain Illumina customers executed long-term supply agreements with Illumina to quell their concerns about the Transaction, (deSouza (Illumina) Tr. 2290); and after Illumina published the original Open Offer, Illumina amended the Open Offer to address additional concerns customers and Complaint Counsel raised during the course of the trial, (deSouza (Illumina) Tr. 2407–09).

Response to Finding No. 1252

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). As such, the proposed finding should be disregarded as solely based on Mr. deSouza's testimony. Further, Mr. deSouza does not have foundation to speak to the state of mind of Illumina's customers. [redacted]

[redacted] Moreover, the evidence shows that the open offer will not resolve potential harms. (CCFF § VIII(A)(3)). Therefore, this Court should disregard the proposed finding.

1252.1 Complaint Counsel also attempted to undermine the benefits of the Open Offer but Mr. deSouza reaffirmed that Illumina is committed to abiding by the terms of the Open Offer and to treating all its oncology customers equally. (deSouza, Tr. 2431-41.)

Response to Finding No. 1252.1

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). As such, Mr. deSouza's unsupported, biased testimony should be disregarded. Further, his testimony is irrelevant. Illumina's "commitment" to abiding by the terms of the open offer is irrelevant given Illumina's clear post-Acquisition incentives. (CCFF ¶ 4192) ("[I]f the incentives aren't right, then the contract is not going to be successful . . . the parties try to build in the protection that they think they can get into the contract, but the real details of how the business is going to work evolve from appropriate business incentives shared by the parties."). Moreover, as explained throughout Complaint Counsel's post-trial briefing, the Open Offer has a myriad of flaws which provide Illumina with mechanisms to disadvantage Grail's rivals. (Complaint Counsel's Post-Trial Brief at 159-180); (Complaint Counsel's Post-Trial Reply Brief at Section IV.). Therefore, this Court should disregard the proposed finding.

1253. Mr. deSouza explained that the Open Offer is a 12–year-long contract that Illumina has made available to any oncology customer and contractually commits Illumina to, among other things, guarantee to oncology customers the same access to products and services as GRAIL or any other Illumina customer, (deSouza (Illumina) Tr. 2400–01); and an oncology

customer who enters into the Open Offer can exit the agreement at any time for any reason, but Illumina cannot exit the agreement, (deSouza (Illumina) Tr. 2402).

Response to Finding No. 1253

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). As such, Mr. deSouza's unsupported, biased testimony should be disregarded. Further, the actual language of the Open Offer contradicts Mr. deSouza's statements and shows there are multiple ways that Illumina could favor Grail and disadvantage its rivals. (Complaint Counsel's Post-Trial Brief at 159-180); (Complaint Counsel's Post-Trial Reply Brief at Section IV.). For example, the Open Offer states that a customer shall have "access to the same product services and support services for purchase" as Grail. (CCFF ¶ 4495). [redacted] For instance, as Illumina's own executive admits, customers would not know how fast its competitors receive service and support from Illumina. (CCFF ¶¶ 4499, 4505); *see also* (CCFF ¶ 2919) (Guardant's Getty testifying that Illumina could easily say things like "'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively."). The weight of the evidence contradicts Mr. deSouza biased, unsupported statement and instead shows that the

Open Offer is insufficient to restore competition to pre-Acquisition state. Therefore, this Court should disregard the proposed finding.

1254. Mr. deSouza testified that to ensure that Illumina cannot offer disadvantageous pricing to any potential GRAIL rival: Illumina commits in the Open Offer to publish the products and services that GRAIL purchased, publish the pricing sheet that Illumina provided to GRAIL, participating in bi-annual audits to ensure compliance, and engage in binding arbitration to resolve any disputes, (deSouza (Illumina) Tr. 2402–03); the Open Offer contains a universal pricing grid, the purpose of which is to provide transparency around the prices that GRAIL is paying for products and services that that GRAIL purchases from Illumina, aid customers in developing multiyear business plans and ensure customers that everyone is on an even playing field, (deSouza (Illumina) Tr. 2403–04).

Response to Finding No. 1254

[redacted]

[redacted]

1255. Mr. deSouza testified that the Open Offer commits Illumina to providing customers with access to any products GRAIL has access to within five days of GRAIL having access to the products. (deSouza (Illumina) Tr. 2407–08.)

Response to Finding No. 1255

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will

consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). As such, Mr. deSouza's unsupported, biased testimony should be disregarded. Mr. deSouza's testimony is also incorrect. Grail can still get advanced notice of advances in Illumina technology or anticipated updates prior to a new product design being finalized. (deSouza (Illumina) Tr. 2432-33). As explained in Complaint Counsel's post-trial briefing, MCED test developers would have no way of knowing whether Grail has advanced notice of a product. (Complaint Counsel's Post-Trial Brief at 192). As such, the evidence shows that this is an unenforceable provision that does not adequately protect Grail's rivals. Therefore, this Court should disregard the proposed finding.

1256. Mr. deSouza explained that the Open Offer guarantees that Illumina will lower the price of sequencing by at least forty-three percent by 2025. (deSouza (Illumina) Tr. 2403.)

Response to Finding No. 1256

[redacted]

[redacted]

[redacted]

1257. Mr. deSouza noted that the Open Offer commits Illumina to enter into IVD agreements with customers who want to enter IVD agreements and support customers in developing an IVD if the customer wants to develop an IVD. (deSouza (Illumina) Tr. 2404.)

Response to Finding No. 1257

The proposed testimony is unsupported, misleading, and against the weight of the evidence. As an employee and shareholder of Illumina, Mr. deSouza stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. As Mr. deSouza explained, his bonus is teed off of performance figures such as revenue and earnings per share. (PX7072 deSouza (Illumina) IHT at 259). The Board of Directors will consider whether this acquisition is successfully consummated in awarding his bonus. (PX7072 deSouza (Illumina) IHT at 259). As such, Mr. deSouza's unsupported, biased testimony should be disregarded. The proposed finding is misleading to the extent it implies that terms referred to in the Open Offer are guaranteed to be included in an executed Illumina IVD agreement. The Open Offer contains a rubric outlining what may be included in the three levels of IVD agreements. The Open Offer, however, does not include the actual IVD agreement a customer can sign. (*See* PX0064 at 028-40 (Illumina Open Offer Agreement, Mar. 29, 2021)). Thus, it is unclear what the final terms of an IVD agreement will entail.

The proposed finding is also misleading to the extent it implies that customer monetary payments under the Open Offer's IVD agreement rubrics are insignificant amounts. The IVD agreement rubric provided in the Open Offer requires customers to pay tens of millions of dollars

and requires customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). For example, if a customer wants to develop an "unlimited" amount of IVD test kits, the customer will have to pay a $25 million tech access fee, development milestone payments of $1 million per IVD test kit on the NextSeqDx platform, $5 million per IVD test kit on the NovaSeqDx platform, and an unknown dollar amount per IVD test kit on "future platforms," and a revenue share of 6% of net sales of the IVD test kits. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)). [redacted]

The proposed finding is also misleading to the extent it implies that the Open Offer is sufficient to restore competition lost from the Acquisition. As explained extensively throughout Complaint Counsel's post-trial briefing, Respondents have failed to meet their burden. (Complaint Counsel's Post-Trial Brief at 159-180); (Complaint Counsel's Post-Trial Reply Brief at Section IV.C.). Therefore, this Court should disregard the proposed finding.

1258. Mr. deSouza testified that the Open Offer commits Illumina to license to any oncology testing customer any intellectual property that is licensed to GRAIL or another oncology customer for use in an oncology test. (deSouza (Illumina) Tr. 2405.)

Response to Finding No. 1258

[redacted]

[redacted]

[redacted]

1259. Mr. deSouza explained that the Open Offer commits Illumina to erecting a firewall between Illumina and GRAIL that ensures Illumina cannot share a customer's confidential information with anyone at Illumina or GRAIL who works with GRAIL's business; (deSouza (Illumina) Tr. 2404–05); and that the Open Offer provides audit and binding arbitration mechanisms to ensure Illumina's compliance with the Open Offer, (deSouza (Illumina) Tr. 2405). Mr. deSouza also testified that he was willing to change the arbitration in any way if Complaint Counsel felt it was still insufficient. (deSouza (Illumina) Tr. 2460–61.)

Response to Finding No. 1259

[redacted]

[redacted]

[redacted]

2. **Alex Aravanis**

a. Background

1260. Dr. Alex Aravanis is the Chief Technology Officer and Head of R&D at Illumina. (Aravanis (Illumina) Tr. 1809). Dr. Aravanis's responsibilities include directing the research and product development programs, managing the teams that are responsible for both, and helping develop Illumina's strategies in those areas. He also participates as a member of the executive team representing research and development. (Aravanis (Illumina) Tr. 1809–10).

Response to Finding No. 1260

Complaint Counsel has no specific response to this proposed finding.

1261. In early 2013, Dr. Aravanis joined Illumina as the Senior Director of R&D. At that time, he was responsible for directing and managing research projects and led efforts to develop new sequencing approaches for therapy selection in cancer and noninvasive prenatal testing. He also worked on improvements to fundamental sequencing technologies, new sequencing chemistries, new sequencing detection methods, new materials for using sequencing,

and also development of software to analyze sequencing data. (Aravanis (Illumina) Tr. 1814–15).

Response to Finding No. 1261

This proposed finding is vague as to "improvements to fundamental sequencing technologies." Respondents do not specify which improvements Dr. Aravanis "worked on." As worded, this proposed finding is also confusing as "fundamental sequencing technologies" could potentially apply to more than Illumina's technology. If so, this is misleading. As an employee of Illumina and former employee of Grail, Dr. Aravanis's knowledge is limited to Illumina's sequencing technology. (Aravanis (Illumina) Tr. 1814-15). Therefore, this Court should disregard the proposed finding.

1262. In 2015, Dr. Aravanis served as a cofounder of GRAIL. (Aravanis (Illumina) Tr. 1815.) In March 2016, Dr. Aravanis left Illumina to join GRAIL. Dr. Aravanis served as Vice President of Research and Development. In that role he built, managed and developed the research and development program at GRAIL and was involved in the initial research to develop the Galleri test. (Aravanis Tr., 1817–18.) After a few years, Dr. Aravanis was promoted to Chief Scientific Officer of GRAIL. As Chief Scientific Officer, Dr. Aravanis's duties expanded to include lab operations and clinical development. Dr. Aravanis held that role until he rejoined Illumina in May 2020. (Aravanis (Illumina) Tr. 1818–19.) Dr. Aravanis rejoined Illumina as head of research, he then became Chief Technology Officer in June of 2020 and head of product development in May of 2021. (Aravanis (Illumina) Tr. 1810.)

Response to Finding No. 1262

Complaint Counsel has no specific response to this proposed finding.

1263. Dr. Aravanis has a bachelor's degree in electrical engineering from the University of California at Berkeley. He also holds a master's and a Ph.D in electrical engineering, and a medical degree from Stanford University. (Aravanis (Illumina), Tr. 1810–11.) After graduating from Berkeley, and prior to joining Illumina, Dr. Aravanis amassed experience working in laboratories and medical device companies. He oversaw research and development at Pria Diagnostics, a company developing an at-home diagnostic fertility and thyroid hormone test, and Epoc Biosciences, a company developing medical devices for intensive care patients. He also served as Chief Scientific Officer at Sapphire, a company developing synthetic biology tools. (Aravanis (Illumina), Tr. 1812–13.) Dr. Aravanis has over 20 U.S. patents and 40 U.S. patent applications in his name and hundreds internationally. (Aravanis (Illumina) Tr. 1820.)

Response to Finding No. 1263

This proposed finding is vague as to what is meant by "amassed experience." Therefore, this Court should disregard the proposed finding.

b. Testimony

1264. Background on DNA and Sequencing. Dr. Aravanis provided background facts on DNA, genes and the genome. (Aravanis (Illumina) Tr. 1823–27.)

Response to Finding No. 1264

This proposed finding is vague as to what is meant by "background facts" on "genes and the genome." This proposed finding is not a standalone "fact" but a heading for the proposed findings below and should be disregarded.

1265. He explained that DNA sequencing is a technology to read DNA; there are many purposes of DNA sequencing in almost every area of life science or clinical medicine; and a good application is finding the right therapy for a cancer patient. (Aravanis (Illumina) Tr. 1827–28.)

Response to Finding No. 1265

This proposed finding is vague because Respondents do not describe what is meant by "many purposes" or by a "good application." Therefore, this Court should disregard the proposed finding.

1266. Dr. Aravanis noted that Next-Generation Sequencing ("NGS") is a higher throughput type of sequencing; first generation sequencing might be able to sequence a hundred molecules on one instrument per run; NGS instruments today can simultaneously sequence millions or even billions of sequences in a single run; there are many applications to NGS for different areas of science and medicine with new applications being published almost every day; some exciting clinical applications for NGS are currently being used, for example therapy selection, but even in those areas there is a long way to go to get the full benefit of the technology; it is still early in seeing how NGS can benefit medicine (Aravanis (Illumina) Tr. 1841–42).

Response to Finding No. 1266

Complaint Counsel objects to this proposed finding to the extent Dr. Aravanis's testimony is providing an expert opinion about all potential applications of NGS sequencers. Dr. Aravanis is a fact witness with knowledge about Illumina's sequencers and Grail's MCED test.

He is not an expert witness qualified to provide opinion testimony about NGS sequencing broadly. This proposed finding is also vague and confusing. It is unclear what "exciting clinical applications" or what the "full benefit" of NGS technology means.

Lastly, this Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This makes it difficult for Complaint Counsel to assess the credibility of each statement included in the above proposed finding. Furthermore, Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46.

1267. Dr. Aravanis described the different oncology applications for which sequencing is used today including: many research applications where people sequence cancer cells to understand cancer biology and how cancer is behaving and how you might treat it; therapy selection applications where you sequence a tumor to understand whether or not any of the mutations that are present might be targetable by a drug; applications for monitoring, sometimes called minimal residual disease, used to determine how effective the treatment will be for a given cancer patient; early cancer detection in individuals who are asymptomatic and do not have cancer (Aravanis (Illumina) Tr. 1843).

Response to Finding No. 1267

Complaint Counsel objects to Dr. Aravanis's testimony in this proposed finding to the extent Dr. Aravanis is providing expert opinion testimony. Dr. Aravanis is a fact witness with knowledge about Illumina's sequencers and Grail's MCED test based upon his current role at Illumina and his former role at Grail. He is not an expert witness qualified to provide opinion testimony about the use of NGS in oncology broadly. Additionally, the proposed finding is vague and confusing. It is unclear what "many research applications" means. It is also

confusing to the extent Respondents are combing scientific research applications in a laboratory and clinical uses of NGS sequencing.

Furthermore, this Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This makes it difficult for Complaint Counsel to assess the credibility of each statement included in the above proposed finding. Furthermore, Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46.

1268. He testified regarding the Illumina sequencing work flow: the first step is to isolate and extract DNA; the second step is called library prep, which consists of preparing the DNA in special ways, and the last step is sequencing the DNA and analyzing the data. (Aravanis (Illumina) Tr. 1829–33.) He also testified that it is possible to process multiple DNA samples at the same time on the same flow cell (Aravanis (Illumina) Tr. 1829–33) and that the consumables, the chemistries and flow cells used in sequencing are not customized, they are generic (Aravanis (Illumina) Tr. 1842).

Response to Finding No. 1268

[redacted]

[redacted]

1269. He explained that the sequencer itself is entirely generic and that the tailoring for a cancer application versus genetic disease testing is all about library prep and data analysis; different MCED tests would use the same instrument and consumable; the unique aspects of any given MCED test would be in the up-front workflow or after the sequencer when analyzing the data. (Aravanis (Illumina) Tr. 1832–33; 1837–40.)

Response to Finding No. 1269

Complaint Counsel objects to this proposed finding as containing improper expert opinion, unreliable, misleading, and vague. Dr. Aravanis is a fact witness with knowledge about Illumina's sequencers and Grail's MCED test. He is not an expert witness qualified to provide opinion testimony about the workflow of NGS sequencers generally. This Court should disregard any opinion about NGS sequencing workflow as improper expert opinion. Furthermore, Dr. Aravanis's testimony is unreliable because he lacks foundation to opine on "any" MCED test developer's workflow. Dr. Aravanis admitted that he has no access to any MCED company's confidential or proprietary information, which would include workflows

established surrounding their specific MCED test. (Aravanis (Illumina) Tr. 1972-77).

Moreover, to the extent Respondents are using Dr. Aravanis's testimony in this proposed finding to minimize the difficulty MCED developers face when switching NGS platforms, it is misleading. Substantial evidence in this matter shows that switching to another NGS platform would cause significant delays, require significant costs, and pose regulatory and financial risks for MCED test developers. (*See* CCFF ¶¶ 1768-1901). MCED tests are developed to run on a specific NGS platform. (*See* CCFF ¶¶ 1768-79). [redacted] Illumina, Grail, and other NGS market participants recognize high switching costs. (*See* CCFF ¶¶ 1840-71). Switching NGS platforms is even more difficult once the MCED test has begun the FDA approval process. (*See* CCFF ¶¶ 1872-1901).

This proposed finding is also vague and confusing because Respondents do not define the term "generic." [redacted] This proposed finding is misleading to the extent it implies "entirely generic" means that the sequencers themselves are interchangeable with each other no matter the application. Additionally, this proposed finding is vague because Respondents do not describe how library prep and data analysis is "tailored" differently. Furthermore, this proposed finding is unreliable to the extent Respondents are relying on this proposed finding as evidence of how "any" MCED test developer must adjust its workflow in using Illumina's sequencer, or any other sequencer. Therefore, this Court should disregard the

proposed finding.

1270. Illumina's Business. Dr. Aravanis testified as to Illumina's business model, including that Illumina develops and commercializes genomics technologies for the purposes of basic research and clinical applications and that Illumina's mission is to unlock the power of the genome, which means understanding how human biology and diseases work and detecting diseases earlier. (Aravanis (Illumina) Tr. 1821.)

Response to Finding No. 1270

The proposed finding is misleading to the extent that it implies Illumina prioritizes "unlocking the power of the genome" over profit. Illumina is a public company whose goal is maximizing revenue for its shareholders. [redacted] When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it does not make business sense for Illumina to sacrifice its revenues solely to altruistically "unlock the power of the genome." Therefore, this Court should disregard the proposed finding.

1271. Dr. Aravanis testified that: "Illumina's core business is to constantly innovate, improve sequencing, you know, create new sequencing technologies, develop them and commercialize them so that, you know, these customers who want to do science, who want to do clinical applications are -- have better and better tools to unlock the genome." (Aravanis (Illumina) Tr. 1844.) "[B]y making the technologies that enable the information the -- the genome to be accessed, at lower cost, with more accuracy, with more speed and in different ways we feel furthers that mission of unlocking the power and ultimately improving human health." (Aravanis (Illumina) Tr. 1821.)

Response to Finding No. 1271

The proposed finding is misleading to the extent that it implies Illumina prioritizes "unlocking the genome" over profit. Illumina is a public company whose goal is maximizing revenue for its shareholders. [redacted]

[redacted] When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it does not make business sense for Illumina to sacrifice its revenues solely to altruistically "unlock the genome." Therefore, this Court should disregard the proposed finding.

1272. Illumina sells eight instruments: the NovaSeq 6000, the NextSeq 1000/2000, the NextSeq 550, the MiSeq, the MiniSeq, the iSeq 100, the NextSeq 550Dx, and the HiSeqDx. (Aravanis (Illumina) Tr. 1845.)

Response to Finding No. 1272

Complaint Counsel has no specific response to the proposed finding.

1273. Dr Aravanis explained that consumables are the materials consumed in a sequencing run; consumables include liquid reagents; for each instrument Illumina sells there are a handful of different consumables. (Aravanis (Illumina) Tr. 1845-46.)

Response to Finding No. 1273

This proposed finding is vague because it does not describe what is meant by "a handful of different consumables." Therefore, this Court should disregard the proposed finding.

1274. Dr. Aravanis noted that flow cells are glass slides where the actual sequencing is done; they have evolved over time, getting larger with more surface area to do more sequencing on the, the density has increased so that the number of DNA sequences you can have on a small area are increased. (Aravanis (Illumina) Tr. 1847.)

Response to Finding No. 1274

This proposed finding is vague and confusing. It is not clear whether Dr. Aravanis's testimony applies to only to the size and density of Illumina's flow cells or the size and density of flow cells for all NGS sequencers more broadly. Therefore, this Court should disregard the proposed finding.

1275. The Founding of GRAIL. Dr. Aravanis testified that the idea for GRAIL came from a couple of projects that Illumina was doing. (Aravanis (Illumina) Tr. 1869–77.)

Response to Finding No. 1275

This proposed finding is vague as Respondents do not describe what is meant as "a couple of projects." Therefore, this Court should disregard the proposed finding.

1276. *First*, Illumina was operating Verinata, a noninvasive prenatal testing business Illumina had recently purchased, and in the first hundred thousand women that received that noninvasive prenatal test some unusual signs were identified. It turned out these signals were undiagnosed cancer. This led to the discovery that cancer detection from the blood might be possible. (Aravanis (Illumina) Tr. 1869.)

Response to Finding No. 1276

The proposed finding is incorrect, misleading, and against the weight of the evidence to the extent that it implies Illumina "discovered" MCED testing. [redacted] Therefore, this Court should disregard the proposed finding.

1277. Dr. Aravanis explained "the laboratory director at Illumina who was responsible for the testing collected these unusual signals. She approached leadership at Illumina about them, including the chief medical officer and also myself, you know, and told us, you know, that we should look into it in more detail. We ultimately formed a team and a program to, you know, evaluate these signals, to follow up with patients carefully and their prescribing physicians, which eventually led to the discovery that these women had undiagnosed cancers." (Aravanis (Illumina) Tr. 1869–70.)

Response to Finding No. 1277

This proposed finding contains unreliable hearsay evidence, is incorrect, misleading, and against the weight of the evidence.

The proposed finding is incorrect, misleading, and against the weight of the evidence to the extent that it implies that Illumina "discovered" MCED testing. [redacted]

To the extent Respondents are relying on Dr. Aravanis's testimony about what Illumina's Laboratory Directory told Dr. Aravanis as evidence that Illumina "discovered" MCED testing, that is an out of court statement being asserted for its truth and as such, unreliable hearsay evidence. This Court should accord this testimony no weight and should disregard the proposed finding.

1278. *Second*, Illumina was developing liquid biopsy technology to look at cancer signals in late-stage cancer for the purposes of therapy selection and there was data from that that applied to some early-stage cancer samples that also suggested that early-stage cancer detection might be possible. (Aravanis (Illumina) Tr. 1870.)

Response to Finding No. 1278

The proposed finding is incorrect, misleading, and against the weight of the evidence to the extent that it implies that Illumina "discovered" MCED testing. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1279. Dr. Aravanis testified that Illumina developed a hypothesis that multicancer early detection might be possible but also appreciated the significant amount of research and clinical development would be required; at the time no other companies were exploring development of NGS-based multicancer early detection tests; Dr. Aravanis, the other founders of GRAIL and Illumina's board came to the conclusion that to pursue this application in the research phases and maximize the changes of success it made sense to found GRAIL as an independent company; at the time, the industry was very skeptical about the concept. (Aravanis (Illumina) Tr. 1870–72.)

Response to Finding No. 1279

[redacted]

[redacted]

[redacted]

1280. Dr. Aravanis testified that Verinata would not have pursued this application if they had not been acquired by Illumina; that Meredith Halks-Miller, the laboratory director who had seen the initial signs of cancer in the blood, told him that prior to the acquisition no one at Verinata would listen to her about pursuing this research, that it was a distraction and that Verinata did not have the resources to do this and that but for Illumina no one would have developed a program in this area and without GRAIL this interesting discovery and the potential benefits might never be realized. (Aravanis (Illumina) Tr. 1873–74.)

Response to Finding No. 1280

This proposed finding contains unreliable hearsay evidence, is inaccurate, misleading, and against the weight of the evidence.

Complaint Counsel objects to this proposed finding as unreliable hearsay evidence. Respondents are relying upon an out of court statement by Ms. Halks-Miller to Dr. Aravanis to attempt to prove the factual proposition that somehow Illumina "discovered" MCED testing. This evidence is unreliable hearsay and should be given no weight and this proposed finding be

disregarded.

The proposed finding is incorrect, misleading, and against the weight of the evidence to the extent that it implies that Illumina "discovered" MCED testing. [redacted] Therefore, this Court should disregard the proposed finding.

1281. Dr. Aravanis explained that Illumina's ownership interest in GRAIL subsequently decreased to around 20%; at that time the relationship between the companies became one of vendor and important customer; that Illumina's interest eventually dropped to 12%; that aside from certain holdover projects there were no further interactions between the companies aside from vendor and customer; Illumina did not customize NGS products for GRAIL prior to the spinout and only did minor customization after the spinout. (Aravanis (Illumina) Tr. 1876–77.)

Response to Finding No. 1281

[redacted]

[redacted]

[redacted]

1282. Development of the Galleri Test. Dr. Aravanis testified that he wrote the research and development plan and led the research and development program to develop Galleri. (Aravanis (Illumina) Tr. 1877.)

Response to Finding No. 1282

This proposed finding is vague as "research and development" is a broad term and Respondents make no attempt to describe it with more clarity. Therefore, this Court should disregard the proposed finding.

1283. Dr. Aravanis explained that the steps involved in developing an MCED test are a research phase, a test development phase, a clinical trial and a commercial launch. (Aravanis (Illumina) Tr. 1878.)

Response to Finding No. 1283

Complaint Counsel objects to this proposed finding to the extent this testimony applies to the development of any other MCED test besides Galleri as unreliable because it lacks foundation. Dr. Aravanis is a fact witness testifying about the development of Galleri in his capacity as a former employee of Grail. He has no basis to testify about the development of any other MCED test. He is not qualified as an expert witness testifying about the development process of MCED tests generally. Therefore, this Court should disregard the proposed finding.

1284. Dr. Aravanis testified that the research phase for Galleri was a multiyear process involving hundreds of employees that included: understanding the types of signals in every major cancer; looking at tens of millions of biomarkers, including mutations, chromosomal changes, RNA signals; recruiting hundreds of individuals for each major cancer type and stage and recruiting individuals without cancer and determining the technology needed to effectively detect the signal. (Aravanis (Illumina) Tr. 1878–81.)

Response to Finding No. 1284

This proposed finding is vague by not quantifying "multi-year" and not describing what is meant by "determining the technology" needed to detect the signal. It is also unclear what is meant by "biomarker," or "signals." Therefore, this Court should disregard the proposed finding.

1285. Dr. Aravanis explained that the most promising signals were methylation signals; that Galleri uses a million such markers; that it would not be possible to create a test using far fewer methylation markers; that different cancer types do not use the same methylation marker. (Aravanis (Illumina) Tr. 1882–83.)

Response to Finding No. 1285

Complaint Counsel objects to this proposed finding to the extent Dr. Aravanis is offering testimony regarding whether it would be possible for ***any*** company to develop an MCED test that uses fewer methylation markers. Dr. Aravanis is a fact witness testifying about the development of Galleri and the capabilities of Galleri's test based on his role as a former employee of Grail. He is not a qualified as an expert in this matter and any opinion about the development of MCED tests generally should be disregarded. Furthermore, Dr. Aravanis has no foundation to testify factually about what might be possible for other MCED test developers to accomplish. He admitted that he has no access to any confidential or proprietary information from other MCED test developers, which would include whether their assays can detect cancer with fewer methylation markers. (Aravanis (Illumina) Tr. 1972-77). Therefore, this Court should disregard the proposed finding.

1286. Dr. Aravanis testified that the test development phase for Galleri was a multiyear process involving hundreds of employees that included: constructing an assay, including library prep and analysis that performs the test, finding or inventing the right chemistries to manipulate and prepare the DNA, miniaturizing the relevant processes, developing an analysis of the signals and verifying and validating the system. (Aravanis (Illumina) Tr. 1885–86.)

Response to Finding No. 1286

This proposed finding is vague in not defining "multiyear," or explaining the process of

"developing an analysis of the signals" or "verifying and validating the system." Therefore, this Court should disregard the proposed finding.

1287. Dr. Aravanis explained that the GRAIL developed a targeted methylation assay and a method for doing high-throughput automated extraction, a method for library prep, a proprietary machine learning algorithms to take the signals and make a prediction about whether or not a patient has cancer and what type of cancer they have. (Aravanis (Illumina) Tr. 1887.)

Response to Finding No. 1287

This proposed finding is vague and confusing as to what is meant by "targeted methylation" or "high-throughput automated extraction." Also "proprietary machine learning algorithms" is not described clearly. Therefore, this Court should disregard the proposed finding.

1288. Dr. Aravanis testified that in the clinical trial phase GRAIL has released results for the CCGA and PATHFINDER studies. (Aravanis (Illumina) Tr. 1891.)

Response to Finding No. 1288

[redacted]

1289. The CCGA study initial results showed that multicancer early detection could be possible and that methylation was the most promising result; later results shows that a much lower-cost targeted methylation assay could achieve high performance for multicancer early detection. (Aravanis (Illumina) Tr. 1891.)

Response to Finding No. 1289

[redacted]

1290. The PATHFINDER study showed that in an interventional clinical trial Galleri could find early stage cancer in significant numbers with a low false positive rate and 90% accuracy. (Aravanis (Illumina) Tr. 1891–92.)

Response to Finding No. 1290

This proposed finding is vague and incomplete. The proposed finding is vague because the terms "significant numbers," "low false positive rate," and "accuracy" are ambiguous and undefined. The proposed finding is incomplete because it omits to mention that only interim results had been released for PATHFINDER as of trial.

Based on the published interim results of PATHFINDER, Galleri detected a total of 12 instances of Stage I-III cancer out of a study population of 6,629 participants. (RX3041 at 005 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). In the same population, Galleri generated 36 false positive results. (RX3041 at 004). Galleri was thus three times as likely to provide a falsely negative result as it was to detect "early-stage" cancer (defining that term broadly to include Stage I-III cancers).

Over half the positive results in PATHFINDER with diagnostic resolution were

determined to be false positives (55.4%) and 25 percent of participants who received falsely positive results underwent at least one invasive procedure. (RX3041 at 004).

1291. Dr. Aravanis testified that there are two ways to commercially launch a test: a laboratory developed test or LDT and an FDA-approved IVD. (Aravanis (Illumina) Tr. 1892.)

Response to Finding No. 1291

[redacted]

1292. GRAIL launched the Galleri test as an LDT in June of 2021; GRAIL chose to launch as an LDT to make the potentially lifesaving technology available as soon as possible and because data from an LDT could be used to support and supplement a PMA application; GRAIL plans to seek FDA approval through a PMA because it will help with reimbursement and adoption. (Aravanis (Illumina) Tr. 1892–93.)

Response to Finding No. 1292

This proposed finding is vague as to what is meant by "help with reimbursement." For additional context, Grail's Chief Medical Officer Joshua Ofman testified "we don't expect that large U.S. payers are going to provide coverage for the [Galleri] test without FDA approval." (Ofman (Grail) Tr. 3319-20). Therefore, this Court should disregard the proposed finding.

1293. Dr. Aravanis testified that GRAIL considered developing a single cancer test as a route to multicancer but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests could take four or five years for each cancer; in order to develop a 50–cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a 50 cancer test directly by undergoing a much larger process that developed a test for 50 cancers at the same time. (Aravanis (Illumina) Tr. 1895–97.)

Response to Finding No. 1293

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1294. Dr. Aravanis testified that it would be difficult to develop a test by simply collecting samples from sample banks without a clinical trial because you would end up finding signals that are an artifact of the collection methods. (Aravanis (Illumina) Tr. 1899–1901.)

Response to Finding No. 1294

[redacted]

[redacted]

1295. The Galleri Test. Dr. Aravanis testified that the Galleri test works by detecting methylation signals in the blood that are coming from a cancer, it the predicts whether or not there is a cancer present or not and the type of cancer and a report is provided to the patient. (Aravanis (Illumina) Tr. 1901–02.)

Response to Finding No. 1295

This proposed finding is an overly broad and vague statement about the Galleri test.

Therefore, this Court should disregard the proposed finding.

1296. He explained that the Galleri test can detect 50 types of cancer; it can detect every major cancer including lung, stomach, head and neck, liver, ovarian and pancreatic cancer. (Aravanis (Illumina) Tr. 1894–95, 1902.)

Response to Finding No. 1296

[redacted]

[redacted]

[redacted]

[redacted]

1297. The specificity of the marketed version of Galleri is 99.5%, which is higher than the specificity of other screening tests that are in the 80s or low 90s. (Aravanis (Illumina) Tr. 1903.)

Response to Finding No. 1297

This proposed finding is vague and misleading. Respondents do not identify what "other screening tests" Dr. Aravanis is referring to as a comparator. It is clear from omitted context of the cited testimony that "the other" screening tests Dr. Aravanis is comparing Galleri to in this testimony are traditional screening tests for individual cancers such as a mammogram. (Aravanis (Illumina) Tr. 1903) ("Q:[H]ow does [Galleri's specificity] compare to the specificity of other screening tests? A: It's very high. I'm not aware of any screening tests with such a high specificity. Most screening tests are, you know, in the 80s or low 90s, not 99.5 percent. A. What's the specificity, if you know, of a mammogram? A: I think it's in the high 80s."). This proposed finding is misleading to the extent it implies that Galleri's specificity is higher than other MCED tests in development, or even other liquid biopsy tests.

This proposed finding is also misleading because Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (*i.e.,* in an asymptomatic screening population). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating:

"to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). CCGA did not involve a real-world population but rather was a case-control study that assessed Galleri's ability to detect cancer signals in individuals who had already been diagnosed with cancer. (*See* CCFF ¶¶ 6238-6241). Results from CCGA-3 are thus not informative of how Galleri would actually perform when used in its intended use population (*i.e.,* in an asymptomatic screening population). Therefore, this Court should disregard the proposed finding.

1298. The sensitivity of the marketed version of Galleri varies by cancer type and stage; the sensitivity for the subgroup of particularly deadly cancers in early stages is 70 percent. (Aravanis (Illumina) Tr. 1904.)

Response to Finding No. 1298

[redacted]

[redacted]

1299. Dr. Aravanis testified that Galleri has detected cancer in asymptomatic individuals and actually resulted in curative therapy for certain patients. (Aravanis (Illumina) Tr. 1904.)

Response to Finding No. 1299

[redacted]

[redacted]

1300. Other Purported MCED Tests. Dr. Aravanis testified that there are several obstacles to developing a test like Galleri: it is not possible to perform a discovery study for an MCED test like Galleri using samples stored in a biobank; you need samples that were actually collected that are relevant to what you are trying to detect, including early stages of specific cancers which are rarely found in biobanks; it would be difficult to develop an MCED test using biomarkers identified from a commercial MRD or therapy selection tests because they focus on a small number of cancers and later stage cancers; there are few precedents for running clinical trials for cancers that do not currently have screening methodologies. (Aravanis (Illumina) Tr. 1915–18.)

Response to Finding No. 1300

[redacted]

[redacted]

[redacted]

[redacted]

1301. Dr. Aravanis testified if a company was within five years of launching an MCED test Dr. Aravanis would expect to see reports, publications, meeting presentations, clinical trials registered on ClinicalTrials.gov and peer reviewed publications; he would also expect a company to disclose that it obtained an investigational device exemption; it would take a couple of years from registration on ClinicalTrials.gov to actual results. (Aravanis (Illumina) Tr. 1908–15.)

Response to Finding No. 1301

[redacted]

[redacted]

[redacted]

1302. Dr. Aravanis testified that he keeps track of other companies developing cancer screening tests and that: there appear to be some tests in early research phases; he is not aware of any tests that are comparable to Galleri; he is not aware of any tests comparable to Galleri that have disclosed a clinical trial on ClinicalTrials.gov; he is not aware of any peer-reviewed articles that describe a test that does what Galleri does; it turns out that companies that Illumina had at

one time tracked as potential competitors to Galleri are not in fact developing anything that would be a substitute or a competitive product. (Aravanis (Illumina) Tr. 1908–20.)

Response to Finding No. 1302

[redacted]

[redacted]

1303. Dr. Aravanis explained that Galleri does not compete with any single cancer tests because they are intended to be used in current standard of care applications while Galleri is not; Galleri is unlikely to compete with cancer tests detecting less than 10 cancers; Galleri will not compete with a test that does not identify tumor of origin because they would be used in a different clinical context, for example with an imaging modality. (Aravanis (Illumina) Tr. 1921–22.)

Response to Finding No. 1303

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1304. Upstream Competition. Dr. Aravanis testified that numerous companies make NGS sequencers including BGI, Thermo Fisher, Oxford Nanopore and Pacific Biosciences and a couple dozen companies are developing NGS sequencing instruments. (Aravanis (Illumina) Tr. 1848.)

Response to Finding No. 1304

This proposed finding is vague as to the term "numerous companies" and inaccurate as to the term "a couple dozen." Dr. Aravanis simply testifies that he "believes" there are a "couple dozen." There is no evidence to support this guess. Dr. Aravanis only mentions two companies and Respondents Proposed Findings of Fact does not mention anywhere near "a couple dozen" companies that purportedly have NGS platforms in development. This proposed finding is also misleading to the extent it implies any of these other NGS platforms either currently on the market or in development are alternatives to Illumina for MCED test developers. [redacted]

Therefore, this Court should disregard the proposed finding.

1305. *Thermo Fisher.* Dr. Aravanis stated that Thermo Fisher makes and instrument called the Ion Torrent; that the Ion Torrent uses a different type of sequencing chemistry and a different detection mechanism than Illumina but it produces similar types of sequencing data; that the Ion Torrent can be us as an alternative for many Illumina applications; that the Ion Torrent platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (Aravanis (Illumina) Tr. 1848–52.)

Response to Finding No. 1305

[redacted]

[redacted]

1306. *BGI.* Dr. Aravanis explained that BGI manufactures multiple sequencing instruments and consumables; they have an array of instruments very similar to Illumina's offerings in terms of the different categories of high throughput , mid throughput, low throughput; the instruments are comparable in terms of sequencing output; BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina; the patents that are currently blocking BGI from entering the U.S. will expire in 2023; Illumina projects BGI will enter the U.S. in 2023. (Aravanis (Illumina) Tr. 1852–54.)

Response to Finding No. 1306

[redacted]

[redacted]

[redacted]

[redacted]

1307. *PacBio.* Dr. Aravanis testified that PacBio has an NGS sequencing product in development that could be used for multicancer screening; PacBio markets its NGS offering as an alternative to Illumina; PacBio's acquisition of Omniome will increase competition for NGS sequencers; PacBio has said that they plan to offer NGS products based on their acquisition of Omniome in 2023 at a very attractive price and that its NGS sequencing will be superior to Illumina. (Aravanis (Illumina) Tr. 1855–56.)

Response to Finding No. 1307

[redacted]

[redacted]

[redacted]

1308. *Oxford Nanopore.* Dr. Aravanis testified that Oxford Nanopore is a company that develops and commercializes NGS products; they are known for a type of sequencing called nanopore sequencing; it is possible to do short-read sequencing on Oxford Nanopore's platforms; doing short-read sequencing on Oxford Nanopore's systems today would be very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (Aravanis (Illumina) Tr. 1856–59.)

Response to Finding No. 1308

[redacted]

[redacted]

g

[redacted]

[redacted]

1309. *Genapsys*. Dr. Aravanis testified that Genapsys is a company that develops and commercializes NGS products; Genapsys sells an NGS instrument and consumable; Genapsys's NGS offering is different from Illumina's but produces the type of data that could be used as a substitute to Illumina for some applications; if Genapsys is able to deliver on its product roadmap then its NGS sequencing product could be used for multicancer screening; Genapsys markets its NGS offering as an alternative to Illumina. (Aravanis (Illumina) Tr. 1860.)

Response to Finding No. 1309

[redacted]

[redacted]

[redacted]

1310. *Singular.* Dr. Aravanis testified that Singular is a public sequencing company developing an NGS sequencing product; they will launch their product in 2023. (Aravanis (Illumina) Tr. 1861.)

Response to Finding No. 1310

[redacted]

[redacted]

[redacted]

1311. *Switching Platforms.* Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and determined that many of them would be a viable alternative. (Aravanis (Illumina) Tr. 1863.)

Response to Finding No. 1311

[redacted]

[redacted]

[redacted]

[redacted]

1312. Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, GRAIL would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

Response to Finding No. 1312

[redacted]

[redacted]

[redacted]

1313. Dr. Aravanis testified that Illumina has projected what the competitive landscape for NGS will look like over the next five to ten years; there are going to be many new sequencing platforms and a tremendous intensification of competition; the many platforms available today will become more competitive and there will be even more platforms in the coming years. (Aravanis (Illumina) Tr. 1866.)

Response to Finding No. 1313

[redacted]

[redacted]

1314. Dr. Aravanis explained that, in large part due to Illumina, the cost of sequencing the genome went from $3 billion to several hundred million dollars to now $600 dollars; Illumina plans to eventually get to a hundred dollar genome. (Aravanis (Illumina) Tr. 1867.)

Response to Finding No. 1314

This proposed finding is misleading to the extent it implies that Illumina's past cost reduction in sequencing is relevant to Illumina's incentives to disadvantage Grail's rivals. [redacted] Complaint Counsel agrees that Illumina's NGS platform technology will not remain stagnant. If Illumina delivers on this plan to continue to innovate and improve the performance of its sequencer, it is even more likely Illumina will retain its position as the dominant NGS platform and no MCED test developer would risk switching to a new – but technologically obsolete – NGS platform. Therefore, this Court should disregard the proposed finding.

1315. Alleged Foreclosure. Dr. Aravanis provided testimony that debunked Complaint Counsel's foreclosure theories.

Response to Finding No. 1315

This proposed finding should be disregarded as unsupported and inaccurate. The proposed finding should be also disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16 C.F.R. § 3.46; Order on Post-Trial Findings). Nonetheless, to the extent Respondents are implying that Complaint Counsel does not dispute Dr. Aravanis's self-serving testimony regarding Illumina's promises to not foreclose Grails' rivals, this proposed finding is inaccurate. (*See* Complaint Counsel's Post-Trial Brief at II.E).

1316. *Raising GRAIL Rivals' Costs*. Dr. Aravanis explained that Illumina does not plan on raising costs to GRAIL's rivals as Illumina's business is based on growing sequencing markets and lowering the cost to allow people to do more sequencing; Illumina plans to decrease costs going forward; foreclosing GRAIL rivals would decrease Illumina's revenue; foreclosing GRAIL's rivals would be very detrimental to Illumina's reputation, would jeopardize current and future customer relationships and would be inconsistent with Illumina's mission and values; customers have alternative sequencing options today. (Aravanis (Illumina) Tr. 1921–27.)

Response to Finding No. 1316

[redacted]

[redacted]

[redacted]

[redacted]

1317. *Small Cost of Sequencing Inputs.* Dr. Aravanis testified to facts showing that Illumina raising the costs of sequencing would be ineffective due to the small percentage of sequencing costs in the overall cost of an MCED test, which facts include: the cost of sequencing is currently less than 10% of revenue from Galleri and will go down to 5% or less in the future; MCED test developers will rely on less sequencing in the future. (Aravanis (Illumina) Tr. 1924–25.)

Response to Finding No. 1317

[redacted]

[redacted]

1318. *Not Cooperating With GRAIL Rivals*. Dr. Aravanis testified that Illumina does not have the ability to harm other test developers by withholding cooperation because: Illumina does not provide more than ordinary course customer support, servicing of instruments and maintenance to customers; a test developer developing an FDA-approved IVD distributable kit with Illumina needs very little support from Illumina; GRAIL is not developing its test as an IVD distributable kit because it believes that an LDT and a site-specific PMA are what the market needs in the foreseeable future. (Aravanis (Illumina) Tr. 1926–28.)

Response to Finding No. 1318

[redacted]

[redacted]

[redacted]

[redacted]

1319. *Optimizing Sequencers for GRAIL*. Dr. Aravanis testified that Illumina does not have any incentive to optimize its sequencing systems that are optimized for Galleri but do not work for a rival third-party test; Illumina has not optimized any of its products for Galleri; Illumina does not have any pattern or practice of optimizing its sequencers for particular applications. (Aravanis (Illumina) Tr. 1928.)

Response to Finding No. 1319

Complaint Counsel objects to this proposed finding because Dr. Aravanis is a fact witness and not qualified to testify as an expert witness. This testimony from Dr. Aravanis is offering an opinion about Illumina's incentives to disadvantage downstream rivals. That is improper expert opinion and should be disregarded. Furthermore, Dr. Aravanis's very brief testimony on this point provides no foundation as to Dr. Aravanis's testimony that Illumina does not have any "pattern or practice" of optimizing its sequencers for particular applications. (Aravanis (Illumina) Tr. 1928 ("Q: As the chief technology officer of Illumina, Doctor, do you know whether the company has a pattern and practice of optimizing sequencers for particular application? A: It does not."). That small, brief statement hardly provides a foundation to testify about any "pattern or practice" – or lack thereof – over a time.

This proposed finding is also vague, inaccurate, and contrary to the weight of the

evidence. This proposed finding is vague because Dr. Aravanis never identifies what is meant by "optimization." Prior to Illumina spinning Grail out, Illumina treated Grail as a "collaborator", co-developing Grail's project development process, assay development workflow, software and data analysis, and designed a kit specially for Grail. (PX2541 (Illumina) at 008 (Interim Review K-2 Grail presentation, Feb. 2, 2017)). Illumina created reagent kits "[p]urpose built for GRAIL" to accommodate Grail's high throughput ctDNA sequencing. (PX2541 (Illumina) at 008, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)). After the spinoff, Illumina provided Grail "RUO kits" instead of the customized kits Grail was originally receiving. (PX2541 (Illumina) at 008, 014 (Illumina, Interim Review K-2 Grail presentation, Feb. 2, 2017)). Whatever Dr. Aravanis means by "optimization," it is clear from the evidence that prior to the spinoff, Illumina gave Grail customized products. Therefore, this Court should disregard the proposed finding.

1320. *Investment in the Market.* Dr. Aravanis testified that Illumina monitors investment in MCED testing; since the announcement of the Transaction multiple companies raise additional money to develop MCED tests and new companies have been founded and financed; Illumina believes the Transaction will significantly increase innovation in the field; impeding innovation would be detrimental to Illumina's reputation, business model and ability to retain talent. (Aravanis (Illumina) Tr. 1931–33.)

Response to Finding No. 1320

[redacted]

[redacted]

[redacted]

1321. *The Verinata Transaction and NIPT.* Dr. Aravanis testified regarding Illumina's experience in the NIPT space which belies the government's assertion that a vertically integrated Illumina will foreclose its rivals. Dr. Aravanis testified that since Illumina's acquisition of Verinata in 2013, Verinata's market share decreased, the cost of NIPT tests decreased by over 90%, the number of tests performed has gone up by a factor of a hundred, the number of companies offering NIPT tests has increased significantly, the coverage of patients for NIPT tests has increased by at least 100 million women and there have been a significant number of new entrants. (Aravanis (Illumina) Tr. 1933–34.)

Response to Finding No. 1321

[redacted]

[redacted]

1322. The Transaction. Dr. Aravanis testified that: In September 2020, Illumina decided to acquire GRAIL; Dr. Aravanis supported the acquisition because if Galleri is widely deployed there is the opportunity to save many thousands of lives, there are few things in cancer diagnostics or therapeutics that have the same potential to avert deaths from cancer, Illumina is

in a unique position to accelerate adoption of the GRAIL Galleri test and by accelerating access to the test many additional thousands of lives will be saved; in addition the Transaction would give Illumina access to additional clinical data and test data that could lead to new breakthroughs and could provide other business benefits. (Aravanis (Illumina) Tr. 1905–06.)

Response to Finding No. 1322

[redacted]

[redacted]

1323. Dr. Aravanis testified that the strategic rationale for the acquisition "[f]irst and foremost was to, through the acquisition, to accelerate the adoption of Galleri, and by doing so, increasing the number of tests, you know, performed for patients by millions than would otherwise happen in the absence of the acquisition, by doing additional millions of tests, potentially saving tens of thousands of additional lives." (Aravanis (Illumina) Tr. 1934.)

Response to Finding No. 1323

This testimony from Dr. Aravanis is self-serving, unfounded, vague, and speculative. Dr. Aravanis never explains how this proposed transaction would allow Illumina to "accelerate the adoption of Galleri" leading to "millions" more tests than without the acquisition. The weight of the evidence demonstrates that [redacted] This Court should not credit this vague, speculative, self-serving testimony from an Illumina executive. Therefore, this Court should disregard the proposed finding.

1324. Dr. Aravanis testified that the decision to reacquire GRAIL was consistent with the decision to spin off and reduce Illumina's stake in GRAIL because GRAIL was set up to do early stage R&D but GRAIL was not set up to do commercial development, regulatory processes; it was always contemplated that Illumina would bring GRAIL back in the future; at this point clinical results and product development have been accomplished and the focus for Galleri will need to be market access and increased R&D resources, which Illumina can provide. (Aravanis (Illumina) Tr. 1907–08.)

Response to Finding No. 1324

[redacted]

[redacted]

[redacted]

1325. Efficiencies. Dr. Aravanis testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies, the elimination of double marginalization, the elimination of the royalty GRAIL owes to Illumina, supply chain and operational efficiencies, and accelerating international availability of Galleri. (Aravanis (Illumina) Tr. 1935.)

Response to Finding No. 1325

[redacted]

[redacted]

1325.1 Complaint Counsel did not challenge any of Dr. Aravanis' testimony on efficiencies. (Aravanis (Illumina) Tr. [redacted], 1971–77.)

Response to Finding No. 1325.1

The proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* 16

C.F.R. § 3.46; Order on Post-Trial Findings). [redacted]

1326. *Saving Lives.* Dr. Aravanis testified that cancer screening from Galleri will significantly reduce the number of cancer deaths because it will enable the ability to screen for 45 cancers that currently have no screening method; Dr. Aravanis authored a study in a peer review journal which estimated that in a population of 100,000 individuals Galleri would find approximately 500 cancers earlier than they would be found otherwise and avert 100 deaths; the PATHFINDER study showed that multiple individuals had early cancers detected by the Galleri test; by accelerating the adoption of the Galleri test by one year approximately 20,000 additional lives could be saved. (Aravanis (Illumina) Tr. 1938–42.)

Response to Finding No. 1326

[redacted]

[redacted]

[redacted]

[redacted]

1327. *Accelerating Market Access to Galleri*. Dr. Aravanis testified that widespread adoption of the Galleri test will require FDA approval and coverage by public payors like Medicare and Medicaid. (Aravanis (Illumina) Tr. 1943.)

Response to Finding No. 1327

[redacted]

[redacted]

[redacted] Complaint Counsel, however, does not otherwise disagree that FDA approval and coverage by public payors like Medicare and Medicaid will result in more widespread adoption of Galleri than pursuing commercialization via an LDT.

1328. Dr. Aravanis explained that in order to get FDA approval GRAIL will need to demonstrate that Galleri was developed and will be operated in accordance or in compliance with FDA quality system regulations and clinical evidence demonstrating the performance of Galleri. (Aravanis (Illumina) Tr. 1943.)

Response to Finding No. 1328

This proposed finding is vague, confusing and misleading. Dr. Aravanis does not describe what is meant by Grail having to demonstrate that Galleri "was developed" and will be operate in "accordance or in compliance" with FDA "quality system regulations." He provides no description of the applicable FDA regulations or process. Nor does he describe how Grail expects the FDA to assess Galleri's performance. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1329. Dr. Aravanis noted that GRAIL has no experience getting FDA approval whereas Illumina received the first FDA clearance for an NGS sequencer, received over 70 clearances and registrations around the world in 45 countries and received multiple clearances and a PMA approval; Illumina has a large regulatory team experienced in FDA submissions, processes, templates, infrastructure for doing and writing and submitting PMA applications; Illumina has broken new ground and learned from past difficulties obtaining FDA approval. (Aravanis (Illumina) Tr. 1943–44.)

Response to Finding No. 1329

[redacted]

[redacted]

[redacted]

1330. Dr. Aravanis testified that Illumina plans to give GRAIL capabilities that are known to be a gap in its regulatory approval, for example, a sophisticated quality management system, support for additional studies, templates and processes that it doesn't have or that are currently deficient; and Illumina can provide these capabilities immediately whereas GRAIL would need to develop them. (Aravanis (Illumina) Tr. 1946.)

Response to Finding No. 1330

[redacted]

[redacted]

1331. Dr. Aravanis testified that payor approval required clinical utility evidence showing the benefit of Galleri. (Aravanis (Illumina) Tr. 1947.)

Response to Finding No. 1331

This proposed finding is vague insofar as Dr. Aravanis does not define what is meant by "payor" nor describe what is meant by "clinical utility evidence." This proposed finding is also misleading to the extent it implies that Grail is not already developing evidence of clinical utility. Like clinical validation, demonstrating clinical utility requires evidence that a test can detect disease in the intended use population. (Qadan (Illumina) Tr. 4110). Establishing clinical utility also involves assessing how a test's results may impact patient management and outcomes. (Qadan (Illumina) Tr. 4110-11). Dr. Navathe testified that because evidence of clinical validity and clinical utility overlap, a single study may develop evidence of both clinical validity and clinical utility, such as Grail's PATHFINDER 1, Clinical Practice Learning Program, Strive, Summit, and NHS studies. (RX3853 (Navathe Trial Dep. at 182)). Therefore, this Court should

disregard the proposed finding.

1332. Illumina has pioneered multiple approaches to market access, resulting in over 100 million additional patients worldwide covered for whole genome testing over the last few years and over 200 million people in the United States receiving coverage for comprehensive genomic profiling. (Aravanis (Illumina) Tr. 1947.)

Response to Finding No. 1332

This proposed finding is vague and confusing. Dr. Aravanis does not identify in this testimony what, exactly, he is referring to that resulted in Illumina gaining over "100 million patients world-wide covered for whole genome testing." He broadly describes it as "multiple approaches to market access" but does not describe those approaches or how they were "pioneering." Dr. Aravanis does not identify the payors Illumina approached, or even the countries involved. Nor does he describe the application of whole genome testing. He also does not describe "comprehensive genomic profiling." Without knowing its purpose or the type of "coverage" Illumina purportedly obtained and from whom, it is impossible to assess whether this claimed expertise is remotely applicable to Galleri. Therefore, this Court should disregard the proposed finding.

1333. GRAIL has no experience in obtaining payor coverage and it would be difficult for GRAIL to gain similar capabilities to Illumina because it lacks the expertise, processes, infrastructure, reputation, track record, size of business that would be required. (Aravanis (Illumina) Tr. 1948.)

Response to Finding No. 1333

[redacted]

[redacted]

1334. Dr. Aravanis testified that Illumina would apply its approaches to market access to Galleri and help it achieve similar success. (Aravanis (Illumina) Tr. 1948.)

Response to Finding No. 1334

[redacted]

[redacted]

1335. Dr. Aravanis testified that the firewall that Illumina has put in place with the Open Offer will not affect the acceleration. (Aravanis (Illumina) Tr. 1946, 1948.)

Response to Finding No. 1335

Complaint Counsel objects to this proposed finding as improper expert opinion. Dr. Aravanis is a fact witness, not an expert witness. His testimony here veers beyond his first-hand knowledge into an opinion about the effect of a firewall provision in Illumina's Open Offer. That is improper expert opinion and should be disregarded. Moreover, he has no basis as fact-witness to speculate about the effect of a proposed firewall. Therefore, this Court should disregard the proposed finding.

1336. Dr. Aravanis testified that GRAIL could not achieve the market access efficiencies by hiring additional personnel because there are only a small number of individuals with direct experience doing NGS submissions, working with the FDA on those types of applications and pioneering market access for NGS products; it would take GRAIL a significant amount of time to hire and train staff for this purpose whereas Illumina has them. (Aravanis (Illumina) Tr. 1968–69.)

Response to Finding No. 1336

Complaint Counsel objects to this proposed finding as improper expert opinion testimony. Dr. Aravanis is a fact witness and not qualified as an expert witness. [redacted] As Grail is currently a customer of Illumina's there is no reason to believe that Grail shares information about its regulatory expertise with Illumina. There is no reason why Dr. Aravanis – an Illumina executive – would have any insight into Grail's current payer access capabilities or plans to expand their capabilities. This Court should disregard this self-serving testimony from an Illumina executive about Grail's current payer access capabilities.

This proposed finding is also misleading by omitting that, to the extent Grail lacks the internal capabilities to pursue payor reimbursement, Illumina is not Grail's only option to obtain that expertise. [redacted] Therefore, this Court should disregard the proposed finding.

1337. *Research and Development Efficiencies*. Dr. Aravanis testified that innovation is incredibly important to Illumina; Illumina invests tremendously in research and development, investing close to 20% of its revenue or $650 million in research and development last year; Illumina's level of R&D is higher than comparable companies in the space; Illumina has approximately 1800 people in the core research and development group and a quarter have advanced degrees. (Aravanis (Illumina) Tr. 1948–50.)

Response to Finding No. 1337

This self-serving testing is unfounded, vague, and misleading. First, Complaint Counsel

objects to Dr. Aravanis's testimony regarding how Illumina's R&D expenditures compare to other companies as unfounded. There is no reason to believe that Dr. Aravanis has any insight into what percentage of another company's revenue it invests into research and development and no means of comparison. Dr. Aravanis also does not identify these "comparable companies," making it impossible to assess the veracity of his testimony. Therefore, this Court should disregard the proposed finding.

1338. Dr. Aravanis testified that the transaction will create research and development efficiencies. *First*, the Transaction will improve the Galleri test because Illumina will be able to apply innovations from other clinical applications to the Galleri test, thereby increasing the clinical value of the test and Illumina will be able to lower the cost of the Galleri test faster by means of its significant experience miniaturizing assays, simplifying assays, developing new components for assays that can lower costs, internalizing manufacturing and reducing the overall cost. (Aravanis (Illumina) Tr. 1951–53). These efficiencies could not be achieved without the Transaction because they would require GRAIL to share its proprietary information with Illumina. (Aravanis (Illumina) Tr. 1953–54.)

Response to Finding No. 1338

[redacted]

[redacted]

1339. *Second*, the Transaction will lead to R&D benefits to the larger Illumina by creating novel discoveries, insights into other types of diseases such as fatty liver disease, diabetes, cardiovascular disease and neurodegenerative disease and significant cross pollination between applications. (Aravanis (Illumina) Tr. 1954–56.) It would be very difficult for GRAIL to pursue these on its own. (Aravanis (Illumina) Tr. 1957.)

Response to Finding No. 1339

[redacted]

[redacted]

1340. Dr. Aravanis also testified that these efficiencies will lead to cost reductions which also occurred when Illumina purchased Verinata in the NIPT space. (Aravanis (Illumina) Tr. 1957–58.)

Response to Finding No. 1340

[redacted]

[redacted]

1341. Dr. Aravanis testified that GRAIL could not achieve the R&D efficiencies by hiring additional employees and experts because creating R&D capabilities takes a substantial amount of time to hire the individuals and develop the programs and teams that can execute on these types of projects. (Aravanis (Illumina) Tr. 1967.)

Response to Finding No. 1341

[redacted]

[redacted]

1342. *Elimination of Royalties*. Dr. Aravanis testified that the Transaction will result in the elimination of the royalty GRAIL owes to Illumina. (Aravanis (Illumina) Tr. 1959.)

Response to Finding No. 1342

Complaint Counsel objects to Dr. Aravanis's testimony on this point as lacking foundation and incomplete. Respondents selectively cited to Dr. Aravanis above. On the very next page of the transcript, when asked if he was personally familiar with all the particulars of that royalty, he responded "I am not." (Aravanis (Illumina) Tr. 1960). This self-serving, speculative testimony from Dr. Aravanis should be disregarded. [redacted] Therefore, this Court should disregard the proposed finding.

1343. *Elimination of Double Marginalization*. Dr. Aravanis testified that Illumina charged a margin to GRAIL on next generation sequencing products prior to the Transaction and GRAIL projected that margin into the future, but the Transaction will eliminate double marginalization. (Aravanis (Illumina) Tr. 1960–61.)

Response to Finding No. 1343

Complaint Counsel objects to Dr. Aravanis's testimony in this proposed finding as improper expert opinion. Dr. Aravanis is a fact witness and not qualified as an expert witness. Any testimony from him about the elimination of "double marginalization" and whether it is verifiable, specific to this transaction, or likely to be passed onto consumers is improper expert testimony and should be disregarded. Moreover, Dr. Aravanis admitted he has no first-hand knowledge of whether the transaction will eliminate double marginalization. In testimony on the same pages Respondents cite above, when asked if he was familiar with "the particulars of the extent to which the transaction will eliminate double-marginalization," Dr. Aravanis responded, "I am not." (Aravanis (Illumina) Tr. 1960). Therefore, this Court should disregard the proposed finding.

1344. *Supply Chain and Operational Efficiencies*. Dr. Aravanis testified to the supply chain and operational efficiencies the Transaction will create, including that: during the due diligence process Illumina identified common suppliers for core components of the Galleri assay which Illumina purchases at a large scale and at volume discounts which it could share with Galleri (Aravanis (Illumina) Tr. 1960–61); Illumina operates multiple clinical laboratories, has operated genomic testing at a very large scale and has developed sophisticated laboratory operations that can be shared with GRAIL to lower their laboratory operations costs and lower turnaround time (Aravanis (Illumina) Tr. 1961–65).

Response to Finding No. 1344

[redacted]

[redacted]

[redacted]

1345. *Expanding International Availability*. Dr. Aravanis testified to facts regarding Illumina's ability to accelerate international availability of Galleri, including: Illumina operates its business in the majority of countries around the world; Illumina has a commercial, regulatory, product support in approximately 100 countries worldwide; Illumina can ship and sell products into all those countries, support products around the globe and pursue regulatory filings and clearances around the world; GRAIL has a small presence in the U.K. with no other international capabilities. (Aravanis (Illumina) Tr. 1965.)

Response to Finding No. 1345

This testimony from Dr. Aravanis is vague and self-serving. Although Illumina may have presence in multiple countries, Dr. Aravanis does not describe how this "footprint" could be applied to MCED tests. [redacted] Dr. Aravanis also does not quantify any costs associated with Illumina expanding its international footprint to accommodate MCED tests into this ability to accelerate Grail's international availability. These broad, vague assertions from a biased Illumina executive are not verifiable and should not be credited. Therefore, this Court should disregard the proposed finding.

1346. Dr. Aravanis explained that international expansion of Galleri will benefit patients in many ways, including: other countries in the world will benefit from the Galleri test much sooner than they otherwise would; a very large number of people around the world can benefit from this; a larger amount of testing will generate significant data on test performance for clinical utility information enabling coverage much sooner and this data can also be used with the FDA to accelerate regulatory approval. (Aravanis (Illumina) Tr. 1963–67.)

Response to Finding No. 1346

This testimony from Dr. Aravanis is vague, self-serving, and incomplete. [redacted] In this testimony, Dr. Aravanis broadly claims that "other countries will benefit" and a "larger amount of data on test performance" would somehow help with "enabling coverage much sooner" and

used to "accelerate FDA approval. Dr. Aravanis, however, does not quantify how much this "extra data" would accelerate payor and regulatory coverage in the United States, nor does he take into consideration any costs associated with expanding access to MCED tests outside of the United States. These broad, vague assertions from a biased Illumina executive are not verifiable and should not be credited.

Moreover, other evidence demonstrates Illumina never seriously considered acceleration of Galleri with payers outside of the United States as a purported efficiency of the transaction until well into the litigation process with the FTC. [redacted] At trial, Illumina's Dr. Qadan testified that he did not analyze how payer adoption outside the United States would impact payor coverage or market access generally in the United States. (Qadan (Illumina) Tr. 4278). Again, this Court should not credit the self-serving testimony of an Illumina executive about a "made for litigation" purported efficiency of the transaction. Therefore, this Court should disregard the proposed finding.

1347. For the efficiencies Dr. Aravanis testified to, he explained that GRAIL would not be able to achieve those efficiencies by contract because "[i]t would require GRAIL to share its knowledge of all of its technology, its assays, its bioinformatics . . . details of its clinical trials, including the results . . . how they were conducted, proprietary information that it wouldn't . . . otherwise share". (Aravanis (Illumina) Tr. 1969–70.)

Response to Finding No. 1347

This proposed finding is vague. Dr. Aravanis broadly states in his testimony that Grail would not be able to achieve these efficiencies by contract with Illumina but he does not connect any of these broad assertions about the need to share "proprietary information" to a specific alleged efficiency. This proposed finding is also misleading by suggesting that any purported efficiencies Illumina now claims will result from the transaction could not be achieved by other

means. The evidence in this matter demonstrates that there are non-merger alternatives Grail could pursue that would achieve the same claimed efficiencies [redacted] Therefore, this Court should disregard the proposed finding.

1348. Open Offer. Dr. Aravanis provided testimony about Illumina's Open Offer and explained that: Illumina has committed that companies may develop similar products to Galleri and others in the oncology space, commits that prices will never be raised; guarantees a price reduction over time of at least 43% (Aravanis (Illumina) Tr. 1926); Illumina cannot disadvantage GRAIL's rivals because the Open Offer requires Illumina to give them access to pre-release NGS products until 45 days after those products are accessible to Galleri (Aravanis (Illumina) Tr. 1930).

Response to Finding No. 1348

[redacted]

[redacted]

[redacted]

3. **Jay Flatley**

a. Background

1349. Mr. Flatley is the former CEO and Executive Chairman of Illumina. (Flatley (Illumina) Tr. 4074–78.)

Response to Finding No. 1349

Complaint Counsel objects to the proposed finding as misleading to the extent it implies that Mr. Flatley has foundation to testify regarding the current business of Illumina as he is no longer involved in the day-to-day operations. (Flatley (Illumina) Tr. 4078). Therefore, this Court should disregard the proposed finding.

1350. Mr. Flatley was CEO of Illumina from 1999 to July 2016, Executive Chairman of the Board of Illumina from July 2016 to January 1, 2020 and Chairman of the Board of Illumina from January 2020 to May 2021. (Flatley (Illumina) Tr. 4074–78.) As CEO, Mr. Flatley was in charge of the overall general management of Illumina. (Flatley (Illumina) Tr. 4076.) As Executive Chairman, Mr. Flatley was a resource to Mr. deSouza, worked on certain special projects, including projects on population genomics, and worked with the market access group. (Flatley Tr. 4076–78.) As Chairman, Mr. Flatley ran board meetings, coordinated overall board room conversation and called for votes of the Board of Directors. (Flatley (Illumina) Tr. 4081.) At the time that the Board voted on the Transaction, Mr. Flatley was chairman of the Board of Directors and coordinated the overall board room conversation about the acquisition and called the ultimate vote to proceed with the deal. (Flatley (Illumina) Tr. 4081.)

Response to Finding No. 1350

The proposed finding is misleading to the extent it implies that Mr. Flatley has foundation to testify regarding the current business of Illumina as he is no longer involved in the day-to-day operations. (Flatley (Illumina) Tr. 4078). The proposed finding is also misleading to the extent it implies that as Chairman of the Board, Mr. Flatley has foundation to opine regarding any alleged benefits of the acquisition or the MCED industry writ large given that any information he received was not based on first-hand experience but rather is solely based on unreliable hearsay given to him by Illumina's biased executives. Therefore, this Court should disregard the proposed finding.

1351. Mr. Flatley is currently the CEO of Zymergen, a materials science company based in California. (Flatley (Illumina) Tr. 4073–74). He also serves on the boards of several companies: Coherent, Denali (working on neurologic therapeutics), Iridia (working on a solution to store data in DNA), Wellcome Leap, and Rivian. (Flatley (Illumina) Tr. 4078–80.)

Response to Finding No. 1351

Complaint Counsel objects to this proposed finding as irrelevant. Mr. Flatley's work at Zymergen, Coherent, Denali, Iridia, Wellcome Leap, and Rivian is irrelevant to any fact at issue in this litigation. As such, this finding should be disregarded.

1352. He is on the board of trustees of the Salk Research Institute in San Diego. Salk is a research center in San Diego that works in plant genomics, an effort to take carbon out of the atmosphere and have plants sequester that carbon in soil. They also perform research in oncology, neurologic, and infectious diseases. (Flatley (Illumina) Tr. 4078–4081.)

Response to Finding No. 1352

Mr. Flatley's work at a company focusing on plants is irrelevant to any fact at issue in this litigation. As such, this finding should be disregarded.

1353. He is also on the advisory board to UC San Diego Moores Cancer Center. The board of advisors meets every couple months to get a report out on what are the latest developments in the cancer research, and for the board to advise the leadership of Moores on how to continue to evolve its cancer research. (Flatley (Illumina) Tr. 4080.)

Response to Finding No. 1353

Respondents have failed to show how his work on the board of advisors at UC San Diego Moores Cancer Center is relevant to any fact at issue in this case. As such, this finding should be disregarded as irrelevant. Moreover, Complaint Counsel objects to the proposed finding as misleading to the extent Respondents are implying that this gives Mr. Flatley foundation to testify regarding MCED tests.

1354. Mr. Flatley has a B.A. in economics from Claremont McKenna College as well as a B.Sc. and M.Sc. in industrial engineering from Stanford University. (Flatley (Illumina) Tr. 4074.) He has spent most of his career in the instrumentation industry including positions at Spectra Physics, Manning Technologies, Plexus Computers, and Molecular Dynamics. (Flatley (Illumina) Tr. 4074–75.)

Response to Finding No. 1354

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1355. The Transaction. Mr. Flatley testified that: after considering the Transaction for quite some time, the Illumina Board of Directors made the final decision to reacquire GRAIL in the fall of 2020; the Board's decision to reacquire GRAIL was unanimous; and the Board voted to reacquire GRAIL because it was a great deal for Illumina's shareholders, had the ability to accelerate the adoption of Galleri and that acceleration was going to be very important in saving lives. (Flatley (Illumina) Tr. 4081–82.)

Response to Finding No. 1355

[redacted]

1356. Efficiencies. Mr. Flatley testified that the Board voted to approve the Transaction because it would result in a number of efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies and accelerating international availability of Galleri. (Flatley (Illumina) Tr. 4082–84.)

Response to Finding No. 1356

The proposed finding is vague give its unclear what "quite some time" means. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Moreover, his testimony was controverted by the overwhelming weight of the evidence. [redacted] Moreover, Mr. Flatley does not have the foundation to testify as to the reason each board member voted for the transaction. [redacted] Therefore, this Court should disregard the proposed finding.

1357. *Saving Lives.* Mr. Flatley testified that the Board concluded that the reunion of Illumina and GRAIL would save lives because it would have a dramatic impact on the rate with which the combined company could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer. (Flatley (Illumina) Tr. 4082, 4089.)

Response to Finding No. 1357

The proposed finding is unsupported by credible testimony and against the weight of the evidence in this case. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Moreover, Mr. Flatley's testimony is not corroborated by any ordinary course documents and Mr. Flatley also lacks the foundation to testify as to what each board member concluded about Illumina's acquisition of Grail. Mr. Flatley is also not best positioned to testify as to whether or

not this merger will generate any efficiencies given that he is removed from the day-to-day operations of Illumina and has no insight into Grail's confidential plans. As such, his testimony should be disregarded.

[redacted] Therefore, this Court should disregard the proposed finding.

1358. *Accelerating Market Access to Galleri*. Mr. Flatley testified that one of the most significant constraints to adoption of a clinical test is reimbursement for that test so that physicians will use the test and ultimately get paid for the test performance; getting FDA approval is challenging, requires a tremendous amount of clinical work, documentation and procedural work and demands that you have the right kinds of relationships and interactions with the FDA; the payor system is quite complicated; there are many different health systems who all operate differently and every country in the world has a different type of payor system, some of those centralized, some of them decentralized like the United States; and the payor system is a very complex matrix or mosaic of people that are involved in getting reimbursement. (Flatley (Illumina) Tr. 4084–85.)

Response to Finding No. 1358

[redacted]

[redacted]

1359. Mr. Flatley explained that Illumina has been developing FDA capabilities inside the company for over a decade; Illumina has invested in the payor area for over a decade; and Illumina has a very large market access group whose sole function is to identify and work with payor groups around the world. (Flatley (Illumina) Tr. 4084–85.)

Response to Finding No. 1359

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Moreover, Mr. Flatley does not have the foundation to testify as to Illumina's market access group. In addition, his testimony is controverted by the testimony of Mr. Qadan – the head of the market access group – who explained that the market access group on consist of 13 employees, only two of which focus on payers partnerships in the United States. (Qadan

(Illumina) Tr. at 4289, 4292). Finally, his testimony is misleading to the extent that it implies that Illumina has the capabilities and expertise to accelerate Grail's payer acceptance. [redacted]

[redacted]

Therefore, this Court should disregard the proposed finding.

1360. Mr. Flatley explained that GRAIL is a very young company with limited resources, a quite limited ability to create an FDA submission and to put Galleri through the process of the FDA and has limited resources to put Galleri through the payor reimbursement process. (Flatley (Illumina) Tr. 4084–85.)

Response to Finding No. 1360

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Moreover, Mr. Flatley does not have the foundation to testify as to Grail's clinical capability given that he does not have access to their confidential information and business plans.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1361. Mr. Flatley testified that Illumina has the ability to accelerate the approval of Galleri through the FDA; that Illumina has to ability to establish reimbursement much more quickly than GRAIL; and that Illumina has the ability to get in front of payors and do submissions and supply clinical data at a rate much faster than GRAIL. (Flatley (Illumina) Tr. 4084–85.)

Response to Finding No. 1361

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently

biased. Moreover, Mr. Flatley does not have the foundation to testify as to Grail's clinical capability given that he does not have access to their confidential information and business plans. Mr. Flatley also does not have foundation to testify as to Illumina's current market access team. And Mr. Flatley certainly does not have the foundation to compare the capabilities of the two.

[redacted] Therefore, this Court should disregard the proposed finding.

1362. *Research and Development Efficiencies.* Mr. Flatley explained that GRAIL is a company with much more limited resources than Illumina; that GRAIL has been focused on delivering Galleri to the market and making that test as advanced as possible as opposed to other avenues of research; and that Illumina has vastly deeper R&D resources. (Flatley (Illumina) Tr. 4088.)

Response to Finding No. 1362

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Moreover, he does not have foundation to testify regarding Grail's focus given that he is not involved in the day-to-day operations of Illumina, nor does he have access to the Grail's confidential business documents. [redacted] Therefore, this Court should disregard the proposed finding.

1363. Mr. Flatley testified that the Transaction will create research and development efficiencies, for example: a combined company would lead to R&D efficiencies that would both improve the existing Galleri test and also improve the speed of development of subsequent tests to Galleri that would address other types of indications (Flatley (Illumina) Tr. 4083); a combined company would accelerate the improvement of the Galleri test by taking advantage of the data

coming from international expansion, integrating the data and using deep learning algorithms to improve the accuracy of the Galleri test and to improve the number of cancers that it addresses (Flatley (Illumina) Tr. 4088); a combined company could delegate resources to work on other tests including other tests involving markers in the blood such as Alzheimers, neurologic diseases and diabetes and bring follow-on, complementary tests to the market much more quickly (Flatley (Illumina) Tr. 4088–89).

Response to Finding No. 1363

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Moreover, he does not have foundation to testify regarding Grail's focus given that he is not involved in the day-to-day operations of Illumina, nor does he have access to the Grail's confidential business documents. [redacted] Therefore, this Court should disregard the proposed finding.

1364. *Supply Chain and Operational Efficiencies*. Mr. Flatley testified to the supply chain efficiencies the Transaction will create, including that: Illumina's supply chain is deep and goes all the way back to primary formulations of products; Illumina and GRAIL both buy significant amounts of reagents and chemicals from third parties; because Illumina and GRAIL use many of the same reagents a combined company would have the ability to combine volumes and reduce the prices paid for those reagents; and a combined company would also have increased purchasing power. (Flatley (Illumina) Tr. 4085.)

Response to Finding No. 1364

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently

biased. Mr. Flatley also lacks the requisite foundation to talk about supply chain efficiencies. Given that his only relation to Illumina is as a board member it belies credulity to think that he could speak with any credibility as to Illumina supply chain or to any alleged efficiencies relating to it. [redacted] Therefore, this Court should disregard the proposed finding.

1365. Mr. Flatley also testified to lab operation efficiencies the Transaction will create, including that: Illumina has several labs around the world; GRAIL has only one lab; integration of those lab operations could lead to much more consistent protocols, much more consistent software, and more consistent lab information management systems; the reunion of Illumina and GRAIL would allow a combined company to integrate and leverage data across multiple tests for a given patient and have much more unified software structures and reporting. (Flatley (Illumina) Tr. 4086.)

Response to Finding No. 1365

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Mr. Flatley also lacks the requisite foundation to talk about supply chain efficiencies. Given that his only relation to Illumina is as a board member it belies credulity to think that he could speak with any credibility as to Illumina lab capabilities or to any alleged efficiencies relating to it. [redacted] Therefore, this Court should disregard the proposed finding.

1366. *Expanding International Availability*. Mr. Flatley testified that Illumina has an international presence in all major countries of the world (Flatley (Illumina) Tr. 4087) and Illumina has a much larger sales force than GRAIL (Flatley (Illumina) Tr. 4083).

Response to Finding No. 1366

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Mr. Flatley also does not have the foundation to testify about the comparative international capabilities of Illumina and Grail. [redacted] Therefore, this Court should disregard the proposed finding.

1367. Mr. Flatley noted that GRAIL has limited resources; plan to launch Galleri only in the US, UK and Canada; and expansion beyond those countries was not even contemplated as an option for the next several years prior to the Transaction. (Flatley (Illumina) Tr. 4087.)

Response to Finding No. 1367

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Mr. Flatley also does not have the foundation to testify about the comparative international capabilities of Illumina and Grail. [redacted] Therefore, this Court should disregard the proposed finding.

1368. Mr. Flatley testified that Illumina would be able to leverage its international presence very directly even if the sales force were separate and that Illumina's infrastructure would dramatically accelerate GRAIL's ability to bring Galleri to other markets of the world and to do that quite quickly. (Flatley (Illumina) Tr. 4087–88.)

Response to Finding No. 1368

The proposed finding is not supported by any reliable testimony and, as such, should be disregarded on that alone. As a shareholder of Illumina, Mr. Flatley stands to gain from Illumina's continued success in both the upstream NGS market as well as in any downstream market. Given his pecuniary interest in this transaction, Mr. Flatley's testimony is inherently biased. Mr. Flatley also does not have the foundation to testify about the comparative international capabilities of Illumina and Grail. [redacted] Therefore, this Court should disregard the proposed finding.

4. **Phil Febbo**

a. Background

1369. Dr. Febbo is currently the Chief Medical Officer at Illumina. (Febbo (Illumina) Tr. 4301.)

Response to Finding No. 1369

Complaint Counsel has no specific response to this proposed finding.

1370. As the Chief Medical Officer, Dr. Febbo oversees Illumina's clinical and medical strategy and he manages the teams that report in to the chief medical officer organization. (Febbo (Illumina) Tr. 4301.) At Illumina, Dr. Febbo has eight functions that reports to him: the medical genomics research, biostatistics, clinical affairs, regulatory affairs, government affairs, payor community affairs, medical affairs and scientific affairs. (Febbo (Illumina) Tr. 4314–16.)

Response to Finding No. 1370

Complaint Counsel has no specific response to this proposed finding.

1371. Prior to Illumina, Dr. Febbo was employed at the Duke University Medical Center where he saw medical oncology patients in the genitourinary oncology clinic for six years and the University of California, San Francisco where he was a professor of medicine in urology and ran a lab that worked on the genomics of cancer. (Febbo (Illumina) Tr. 4302–03.) Dr. Febbo also had previous experiences with clinical trials, the FDA, payors, peer-reviewed publications, and NGS products. (Febbo (Illumina) Tr. 4304–08).

Response to Finding No. 1371

Complaint Counsel has no specific response to this proposed finding.

1372. Dr. Febbo received his bachelor's degree in biology from Dartmouth and he obtained his medical degree from the University of California, San Francisco. After medical school, Dr. Febbo trained in internal medicine and oncology within the Harvard Medical System at the Brigham and Women's Hospital. Furthermore, Dr. Febbo completed a medical oncology fellowship at the Dana-Farber Cancer Institute. (Febbo (Illumina) Tr. 4302.)

Response to Finding No. 1372

Complaint Counsel has no specific response to the proposed finding.

b. Testimony

1373. Background on Regulatory Approval for NGS Products. *Illumina's Clinical, Regulatory and Market Access Expertise.* Dr. Febbo testified that he oversees approximately 160 employees across eight functions, each of which contribute to Illumina's regulatory and market access initiatives: medical genomics research, biostatistics, clinical affairs, regulatory affairs, medical affairs, scientific affairs, government affairs and market access; (Febbo (Illumina) Tr. 4313-14) his team's experience in and expertise with genomics is critical, because Illumina's technology is still relatively new to payors, regulators and governments, so it is important to have experts that can help educate those stakeholders and convince them that NGS tests should be approved and covered. (Febbo (Illumina) Tr. 4317–18.)

Response to Finding No. 1373

Complaint Counsel objects to the proposed finding because it is vague and against the weight of the evidence.

The proposed finding is vague because it does not explain what Illumina's purported "regulatory and market access initiatives" are. The proposed finding's claim regarding "experience in and expertise with genomics" is vague, as it is not clear what relevance it has to developing an MCED test, which is something Illumina has never done. The proposed finding is also vague because it does not explain for what purpose Dr. Febbo's team's purported experience in and expertise with genomics is "critical." The proposed finding is vague because it does not specific the "NGS tests" it references. The proposed finding is vague because it does not identify the purported "experts" referenced.

[redacted]

Therefore, this Court should disregard the proposed finding.

1374. Dr. Febbo provide an overview of each of the functions he oversees: clinical affairs executes on the clinical studies required to support the regulatory filings for clinical tests; regulatory affairs oversees and provides guidance on the those clinical studies; biostatistics ensures the studies are scientifically rigorous and can demonstrate the performance of the tests; medical affairs provides medical input during the development of tests, educates healthcare providers and healthcare provider societies about genomics and generates evidence about the clinical validation and utility of Illumina's tests; scientific affairs develops presentations, abstracts and publications for the studies that Illumina performs, and assists with submissions to payers and regulatory authorities; market access engages with payers to cover Illumina's clinical tests; and government affairs works with governments to advocate for the use of Illumina's technology. (Febbo (Illumina) Tr. 4314–16.)

Response to Finding No. 1374

Complaint Counsel has no specific response to this proposed finding.

1375. *Importance of Clinical Evidence.* Dr. Febbo testified that it is important for an LDT to have clinical evidence that backs its performance: test developers and labs require CLIA certification to offer their tests, and after initial certification, labs undergo routine audits in which the clinical data supporting their tests and the claims that they put on their reports are reviewed; labs put their CLIA license at risk if they don't have sufficient data supporting their tests. (Febbo (Illumina) Tr. 4322–23.)

Response to Finding No. 1375

Complaint Counsel objects to the proposed finding because it is vague and misleading.

The proposed finding is vague because it does not define "clinical evidence" and does not explain what "back its performance" means or in what context that is relevant.

The proposed finding is misleading to the extent it suggests that Grail is unable to operate a CLIA-certified laboratory on its own without Illumina's help. In fact, [redacted]

[redacted]

1376. Dr. Febbo testified that diagnostic tests can obtain payer reimbursement without FDA approval. For instance, NIPT is run exclusively under the LDT framework and is routinely covered by payers. (Febbo (Illumina) Tr. 4323–24.) In addition Dr. Febbo testified that certain breast and prostate cancer therapy selection tests, as well as special stains in pathology are offered as LDTs and regularly reimbursed. (Febbo (Illumina) Tr. 4323–24.)

Response to Finding No. 1376

Complaint Counsel has no specific response to this proposed finding.

1377. Dr. Febbo testified that he has experience switching an LDT from one platform to another, and in his experience, this takes approximately six to 12 months; the process is not that different if the test already has premarket approval from the FDA, but Dr. Febbo testified that you must also submit data to the FDA to secure approval to switch platforms, which could take an additional three to six months. (Febbo (Illumina) Tr. 4325–26.)

Response to Finding No. 1377

Complaint Counsel objects to the proposed finding because it is vague, it lacks foundation, and it is against the weight of the evidence.

The proposed finding is vague because it does not identify the "LDT", "one platform", "or another" referenced.

The proposed finding lacks foundation because it does not establish what specific experience Dr. Febbo purportedly has switching an LDT from one platform to another, nor does it identify the purported test or the purported platforms. There is no evidence Dr. Febbo has experience switching an NGS-based test, much less a liquid biopsy NGS-based test such as an MCED test, from one NGS platform to another NGS platform.

The proposed finding is against the weight of the evidence showing Dr. Febbo lacks

experience relevant to PMAs for NGS-based tests. Since Dr. Febbo joined Illumina in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test (Febbo (Illumina) Tr. 4450-51) and has not even submitted a final PMA application to the FDA for any NGS-based diagnostic test (Febbo (Illumina) Tr. 4451). [redacted]

Therefore, this Court should disregard the proposed finding.

1378. Efficiencies. Dr. Febbo testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies, supply chain and operational efficiencies, and accelerating international availability of Galleri. (Febbo (Illumina) Tr. 4333–75.)

Response to Finding No. 1378

Complaint Counsel objects to the proposed finding because it is confusing, vague, unsupported, and against the weight of the evidence.

The proposed finding is confusing because it strings together multiple unrelated purported facts out of context without providing specific citations for each. This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Respondents' combination of numerous largely unrelated statements is confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' omnibus citation at the end of their recitation of unrelated statements does not provide clear support for any individual statement.

The proposed finding is vague as it does not define or explain "research and development

efficiencies" or "supply chain and operational efficiencies."

The proposed finding is unsupported because it does not cite any evidence showing in which specific countries the international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion would only be achieved through a merger with Illumina.

The proposed finding is against the weight of evidence showing Dr. Febbo has no basis for claiming that Illumina will accelerate Galleri's FDA approval. [redacted] Similarly, Dr. Febbo has no basis for claiming Illumina will accelerate Galleri's market access. [redacted]

The proposed finding also against the weight of the evidence showing that Respondents' purported supply chain efficiencies were developed during the course of this litigation. [redacted] Further, in [redacted]

[redacted] In fact, Illumina ordinary course documents indicate that Illumina did not expect material synergies from COGS or operating expenses as a result of the proposed transaction. *See, e.g.*, [redacted] Therefore, this Court should disregard the proposed finding.

1379. Dr. Febbo explained that this acceleration effect is not reflected in the base case of Illumina's deal model for the merger, because the model was created to determine the acquisition price, and did not reflect the value that Illumina believed it could bring to GRAIL. (Febbo (Illumina) Tr. 4361.)

Response to Finding No. 1379

Complaint Counsel agrees that Illumina did not model acceleration of Galleri into its base case valuation of GRAIL; but otherwise objects to the finding.

The proposed finding is vague because it does not define "this acceleration effect," "the acquisition price," or the "value" referred to.

The proposed finding is confusing because the value of GRAIL to Illumina should logically include all potential value Illumina reasonably believed it could realize from GRAIL. Illumina's exclusion of acceleration from its base case valuation of GRAIL demonstrates that Illumina did *not* believe it could accelerate Galleri.

The proposed finding is against the weight of evidence confirming that at the time of the transaction Dr. Febbo had no basis to reasonably believe that Illumina would accelerate Galleri's FDA approval. [redacted]

[redacted] Similarly, Dr. Febbo had no basis to reasonably believe that Illumina would accelerate Galleri's market access. [redacted] Therefore, this Court should disregard the proposed finding.

1380. *Lives Saved*. Dr. Febbo testified that the efficiencies will accelerate the adoption and availability of Galleri by approximately at least one year (Febbo (Illumina) Tr. 4360) and that he believes the resulting one-year acceleration of access to Galleri will save lives. (Febbo (Illumina) Tr. 4362–63.)

Response to Finding No. 1380

Complaint Counsel objects to the proposed finding because it is vague and against the weight of the evidence.

The proposed finding is vague because it is not clear what "the efficiencies" refers to.

The proposed finding is against the weight of evidence showing Dr. Febbo has no basis for claiming that Illumina will accelerate Galleri's FDA approval. [redacted] Similarly, Dr. Febbo

has no basis for claiming Illumina will accelerate Galleri's market access. [redacted] Therefore, this Court should disregard the proposed finding.

1381. *Accelerating Market Access to Galleri*. Dr. Febbo testified that a single-site PMA approval from the FDA has several benefits: because a PMA requires additional review, additional data and FDA approval it is seen as another assessment of the quality of the evidence supporting the test; the FDA has very strong credibility with which to attest to the safety and efficacy of testing in other areas such as therapy selection where there is now a national coverage decision linked with FDA approval; having a single-site PMA and a companion diagnostic claim compels reimbursement by Medicare. (Febbo (Illumina) Tr. 4337–38.)

Response to Finding No. 1381

Complaint Counsel objects to the proposed finding because Respondents' counsel's out-of-context summary mischaracterizes and does not accurately represent Dr. Febbo's testimony. Therefore, this Court should disregard the proposed finding.

1382. FDA approval of an NGS test is a big challenge for the FDA because the agency is generally used to reviewing a test that measure one or a small number of analytes or variables to determine the state of a patient to help in a single indication and one in which additional education will be needed. (Febbo (Illumina) Tr. 4341–43.)

Response to Finding No. 1382

Complaint Counsel objects to the proposed finding because it is vague, unreliable, and lacks foundation.

The proposed finding is vague as to what "big challenge" means, what "the state of a patient" means, and what "to help in a single indication" means.

The proposed finding lacks foundation because Dr. Febbo does not represent or speak for the FDA.

The proposed finding is unreliable because it is based on hearsay testimony by Dr. Febbo. In the passage cited, Dr. Febbo is offering a description of the what the FDA purportedly has

said in publications or meetings (that context is obscured in the proposed finding), evidence of which is not cited in the proposed finding. This Court should reject the proposed finding because it is unreliable.

1383. Dr. Febbo testified that Illumina has experience clearing both tests and devices with the FDA: Illumina obtained a 510(k) for its cystic fibrosis test, a PMA in cancer therapy selection for the Praxis extended RAS panel, and also cleared the MiSeq Dx and NextSeq Dx sequencers. (Febbo (Illumina) Tr. 4338–39.) Illumina is also in the midst of PMA submissions for its NIPT and therapy selection tests, as well as for a cleared version of its NovaSeq platform. (Febbo (Illumina) Tr. 4339.)

Response to Finding No. 1383

Complaint Counsel objects to the proposed finding because it is against the weight of the evidence and misleading.

[redacted] Illumina's cystic fibrosis test is only a Class II medical device and therefore only required 510(k) clearance from the FDA; it did not go through the Class III premarket approval process. (PX7099 (Febbo (Illumina) Dep.) at 84). Illumina's cystic fibrosis test is not a liquid biopsy test; it only tests for germ line variants, not somatic mutations. (PX7099 (Febbo (Illumina) Dep.) at 85). The number of class III PMA approvals that Illumina holds for NGS-based diagnostic tests can be counted on one finger. The Praxis therapy selection test is Illumina's only an NGS-based diagnostic test with a class III PMA approval. (Febbo (Illumina) Tr. 4445-46). But the Praxis test differs significantly from an MCED test—the Praxis test sequences tumor tissue; it is not a liquid biopsy test; and it does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446). [redacted] Illumina's Praxis test received its PMA from the FDA before Dr. Febbo joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451). Since Dr.

Febbo joined Illumina in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51). Since Dr. Febbo joined the company in 2018, Illumina has not even submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451).

The proposed finding is misleading in its claim that Illumina is "in the midst of PMA submissions" for its NIPT and therapy selection tests. [redacted] Therefore, this Court should disregard the proposed finding.

1384. Dr. Febbo testified that Illumina also has additional experience interacting with FDA officials and educating the agency about NGS technology, including: Illumina officials have held educational sessions about particular aspects of NGS during the "presubmission" stage of the PMA process, and also hosted 15 FDA employees for a two-day onsite session about the different components of NGS, including tutorials on sample preparation, sequencing samples and the back-end bioinformatics work. (Febbo (Illumina) Tr. 4339–41.) In addition, Illumina is a member of BloodPAC, an organization that advocates for the use of NGS-based clinical tests, which the FDA also participates in. (Febbo (Illumina) Tr. 4341.)

Response to Finding No. 1384

Complaint Counsel objects to the proposed finding because it is vague and misleading. The proposed finding is vague because "educating the agency about NGS technology" is nonspecific and does not indicate whether or how it had any relation to MCED testing. The proposed finding is also vague because it does not indicate when Illumina held the purported "educational sessions" nor whether or how these sessions had any relation to MCED testing. The proposed finding is misleading because it does not indicate who are the other member of BloodPAC and whether the membership includes any MCED developers. The proposed finding

is also misleading to the extent it suggests that the FDA either was or remains in need of any "educating" about NGS technology; Respondents and Dr. Febbo are not affiliated with and lack any foundation to speak for the FDA. Therefore, this Court should disregard the proposed finding.

1385. Dr. Febbo testified that as Illumina has taken products through the FDA over the last decade, "we've established a cadence, an understanding. We've helped the FDA understand, and we feel we know where we need to continue to help them move and understand our technology in a way that's scalable and will help realize the potential of precision medicine." (Febbo (Illumina) Tr. 4344.) In addition, Dr. Febbo testified that Illumina's own teams have gained a better understanding of the requirements that are evolving from the FDA, which will also contribute to accelerating Galleri's PMA. (Febbo (Illumina) Tr. 4344.)

Response to Finding No. 1385

Complaint Counsel objects to the proposed finding because it is vague. The proposed finding is vague as to what is meant by "cadence" and "understanding." It is also vague because it does not explain what it is Illumina has purportedly "helped the FDA understand" nor how that was purportedly accomplished. It is also vague because it refers to how Illumina purportedly "feels" about what it "knows." It is also vague because it is unclear what it is that, in Illumina's feeling, the FDA purportedly needs to "move" on. It is also vague as to what it means for the FDA's understanding of Illumina's technology to be "scalable." It is also vague because it does not define or explain what "the potential of precision medicine" means in this context. It is also vague because it does not identify the purported evolving requirements from the FDA that Illumina's teams have purportedly gained a better understanding of, nor whether GRAIL found it as difficult as Illumina did to understand the requirements and thus could benefit from Illumina's increased understanding. It is also vague because it does not provide any detail whatsoever on *how* Illumina's purported improved understanding will purportedly "contribute" to accelerating Galleri's PMA and by how much. Therefore, this Court should disregard the proposed finding.

1386. Dr. Febbo testified that: Illumina's quality management system ("QMS"), which is compliant with FDA and foreign regulators, will also help accelerate Galleri (Febbo (Illumina) Tr. 4346–49); a QMS "is foundational to the work you do to develop, validate, and provide and manufacture a test", as it ensures 'consistency in the manufacturing of a test so that the performance of each test produced is similar to the performance of the test when it was going through clinical validation" (Febbo (Illumina) Tr. 4346–47); it has taken Illumina seven years to develop its QMS, and over that time Illumina has improved and refined its processes as it's gone through routine audits from FDA and other regulators (Febbo (Illumina) Tr. 4347–48); Illumina has "had a quality management system longer than GRAIL's been a company, and so those -- that learning, that evolution, and those -- those procedures and documentations that are foundational to the quality systems, as well as some of the software infrastructure, can be incorporated in the leverage to GRAIL's benefit." (Febbo (Illumina) Tr. 4348–49.).

Response to Finding No. 1386

Complaint Counsel objects to the proposed finding because it is misleading and against the weight of the evidence.

The proposed finding is misleading to the extent it suggests that it would necessarily take other companies the same length of time as Illumina to develop a QMS. Illumina sells instruments, consumables, reagents, and kitted tests; whereas GRAIL performs one single testing service in one laboratory; therefore, it is unclear how Illumina's QMS system is even applicable to GRAIL's business, much less a proxy for how long it would take GRAIL to implement its own QMS.

The proposed finding is against the weight of the evidence showing that Illumina is not unique in having a QMS. Grail's CMO, Dr. Ofman, conceded on cross examination that Illumina is not the only company with a quality management system (QMS) that meets the FDA's standards – and that, in fact, that many companies other than Illumina have quality management systems that have met with FDA approval for IVD tests. (Ofman (Grail) Tr. 3446). Having an FDA-compliant QMS is a requirement to obtain FDA approval(Ofman (Grail) Tr. 3446), which means that every company that has obtained PMA approval for an IVD test must also have an FDA-compliant QMS (Ofman (Grail) Tr. 3446). Therefore, this Court should

disregard the proposed finding.

1387. Dr. Febbo testified that GRAIL does not have FDA experience comparable to Illumina's. (Febbo (Illumina) Tr. 4344.)

Response to Finding No. 1387

Complaint Counsel objects to the proposed finding because it lacks foundation and it is against the weight of the evidence.

The proposed finding lacks foundation because Dr. Febbo does not have personal knowledge regarding GRAIL's FDA experience.

The proposed finding is against the weight of the evidence showing Illumina's FDA experience is lacking. The number of class III PMA approvals that Illumina holds for NGS-based diagnostic tests can be counted on one finger. The Praxis therapy selection test is Illumina's only an NGS-based diagnostic test with a class III PMA approval. (Febbo (Illumina) Tr. 4445-46). But the Praxis test differs significantly from an MCED test—the Praxis test sequences tumor tissue; it is not a liquid biopsy test; and it does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446). Moreover, Illumina was not even the sponsor of the clinical study that the FDA relied on to grant PMA approval for Praxis. (CCFF ¶ 5169). Illumina's Praxis test received its PMA from the FDA before Dr. Febbo joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451). Since Dr. Febbo joined Illumina in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51). Since Dr. Febbo joined the company in 2018, Illumina has not even submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451). Moreover,

[redacted]

[redacted] Illumina has never engaged with the FDA regarding an MCED test. (Febbo (Illumina) Tr. 4451).

The proposed finding is also against the weight of the evidence showing that [redacted] Therefore, this Court should disregard the proposed finding.

1388. Dr. Febbo testified that Illumina's experience will accelerate the FDA approval and PMA process for Galleri and that GRAIL would be able to leverage Illumina's already existing QMS for its own FDA efforts. (Febbo (Illumina) Tr. 4344–45, 4348–49.)

Response to Finding No. 1388

Complaint Counsel objects to the proposed finding because it lacks foundation and is against the weight of the evidence.

The proposed finding lacks foundation because Dr. Febbo does not have personal knowledge regarding GRAIL's FDA experience.

The proposed finding is against the weight of the evidence showing Illumina's FDA experience is lacking. The number of class III PMA approvals that Illumina holds for NGS-based diagnostic tests can be counted on one finger. The Praxis therapy selection test is Illumina's only an NGS-based diagnostic test with a class III PMA approval. (Febbo (Illumina) Tr. 4445-46). But the Praxis test differs significantly from an MCED test—the Praxis test sequences tumor tissue; it is not a liquid biopsy test; and it does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446). Moreover, Illumina was not even the sponsor of the

clinical study that the FDA relied on to grant PMA approval for Praxis. (CCFF ¶ 5169). Illumina's Praxis test received its PMA from the FDA before Dr. Febbo joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451). Since Dr. Febbo joined Illumina in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51). Since Dr. Febbo joined the company in 2018, Illumina has not even submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451). Moreover,

[redacted] Illumina has never engaged with the FDA regarding an MCED test. (Febbo (Illumina) Tr. 4451).

The proposed finding is also against the weight of the evidence showing that [redacted] Therefore, this Court should disregard the proposed finding.

1389. Dr. Febbo explained that Ammar Qadan, who reports to Dr. Febbo, is responsible for the plan to accelerate Galleri's adoption by payors, but testified that Illumina will commit to investing between $500 million and $1 billion over the next five to ten years to generate the clinical evidence necessary to secure broad payor coverage. (Febbo (Illumina) Tr. 4349–51.)

Response to Finding No. 1389

Complaint Counsel objects to the proposed finding because it is misleading and against

the weight of the evidence.

The proposed finding is misleading because it does indicate what GRAIL's standalone plan is to invest in obtaining payor coverage for Galleri. The proposed finding is also misleading to the extent that it suggests Illumina's purported commitment to investing $500 million to $1 billion over the next five to ten years will accelerate Galleri's payor coverage.

The proposed finding is against the weight of the evidence showing Illumina would not accelerate Galleri's payor coverage. Illumina's claimed reimbursement acceleration efficiency is not reflected in the base case of Illumina's deal model. (Febbo (Illumina) Tr. 4360-61). [redacted] Therefore, this Court should disregard the proposed finding.

1390. *Research & Development Efficiencies*. Dr. Febbo testified that there are two categories of R&D efficiencies that the Transaction will generate. *First*, as testing of Galleri scales, the combined company will have access to more data that his biostatistics team and the product development team can use to refine the test and improve its performance over time. (Febbo (Illumina) Tr. 4356–57.)

Response to Finding No. 1390

Complaint Counsel objects to the proposed finding because it is vague and inherently

speculative.

The proposed finding is vague because it does not identify the "data" that Illumina's biostatistics and product development teams will purportedly have access to, nor what it is Illumina can purportedly do with that data that a standalone GRAIL could not. The proposed finding is also vague because it does not explain *any* specific ways in which Illumina, but not GRAIL alone, can purportedly "refine the test" and "improve its performance," nor does it specify the time period over which this would purportedly occur.

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

1391. *Second*, Dr. Febbo testified that Illumina can generate R&D efficiencies relating to new clinical applications, similar to Illumina's early cancer signal discovery with NIPT: Dr. Febbo explained that as the volume of Galleri tests increases, it will become more likely that some outlier signal gets observed, and Illumina has a "growing bench of experts who can look at these outliers, look at these signals, and help determine what's happening" and then take that observation to hypothesis, then proof of concept study and eventually a clinical test. (Febbo (Illumina) Tr. 4357–59.)

Response to Finding No. 1391

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is vague and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by mixing in direct quotes with Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding is vague because it does not identify with specificity the purported "R&D efficiencies" nor the purported "new clinical applications" to which they relate. The

proposed finding is also vague because it does not explain what "more likely" means or specify the time period over which this would purportedly occur. It is also vague as to what is meant by "some outlier signal." It also does not identify the "growing bench of experts," nor what it means for them to "look at these outliers, look at these signals, and help determine what's happening." The proposed finding is also vague because it does not identify the "observation," "hypothesis," "proof of concept study," or "clinical test" referenced.

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

1392. *Supply Chain and Operational Efficiencies*. Dr. Febbo testified that finding the most efficient way to process samples, including through increased automation in a test's workflow, is critical to the success of any clinical test, both because it results in improved analytic performance and decreased operational burden (Febbo (Illumina) Tr. 4334); Illumina has lab operations expertise through its Verinata acquisition and because of that, Illumina has "more experience . . . than any other organization" in scaling a clinical test on Illumina sequencers. (Febbo (Illumina) Tr. 4334.)

Response to Finding No. 1392

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is vague and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by mixing in direct quotes with Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding is vague because it does not identify means of "finding the most efficient way to process samples" other than purportedly "through increased automation in a tests workflow." It is also vague because it does not explain what "critical to the success of any

clinical test," "improved analytic performance," and "decreased operational burden" mean. The proposed finding is also vague because it declares that Illumina has "lab operations expertise" but does not explain what that expertise applies to, where it resides, or how it would be applied to Galleri. It also does not explain how Illumina's purported experience would lead to supply chain and operational efficiencies that GRAIL would otherwise be unable to realize.

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

1393. *Expanding International Availability*. Dr. Febbo testified that Illumina has a significant international presence and experience, including that: Illumina does business in over 120 countries, has regulated products and meaningful reimbursement in over 30 countries, has relationships with international laboratories and health systems, all of which is meaningful experience Illumina can bring to bear to help GRAIL. (Febbo (Illumina) Tr. 4351–52.)

Response to Finding No. 1393

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is vague and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by substituting Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding is vague because it is not clear what "has regulated products and meaningful reimbursement" means, and it does not identify or provide any context for the purported "relationships with international laboratories and health systems." It is also vague as to what "meaningful experience" means and how exactly Illumina can purportedly "bring to bear" that experience to help GRAIL.

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

1394. Dr. Febbo testified that Illumina will be able to accelerate Galleri's international expansion. (Febbo (Illumina) Tr. 4351–53.)

Response to Finding No. 1394

Complaint Counsel objects to the proposed finding because it is vague, conclusory, and speculative.

The proposed finding is vague because it does not provide any details at all about Galleri's "international expansion" that Illumina will purportedly be able to accelerate, such as the countries, time period, studies, or sales that Galleri would purportedly otherwise not achieve but would realize with Illumina.

The proposed finding is conclusory because it simply declares that Illumina "will" be able to accelerate Galleri's international expansion with no additional facts, context, or corroborating evidence whatsoever.

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

1395. Dr. Febbo explained that accelerating Galleri's international adoption will have a positive impact on patients in the United States because: by evaluating the performance of Galleri in countries with ethnic distribution different than the United States, Illumina will be able to better understand Galleri's performance in those populations within the United States, where

they might be underrepresented in clinical studies international expansion will result in a higher volume of real-world evidence on Galleri's performance, which can be used to help convince payors to increase coverage for Galleri. (Febbo (Illumina) Tr. 4353–54.)

Response to Finding No. 1395

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is vague and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by substituting Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding merely assumes without support that Illumina will accelerate Galleri's international adoption.

The proposed finding is vague because it does not define or explain what "positive impact on patients in the United States," "evaluating the performance of Galleri," or "better understand Galleri's performance" means. It also does not identify "those populations within the United States." It also does not define "real-world evidence on Galleri's performance."

The proposed finding is confusing because it seems to contemplate underrepresenting certain populations in Galleri's clinical studies but then somehow using "real-world evidence" (generated from increased international expansion of Galleri that is assumed without any basis) outside the context of a controlled clinical study to somehow "help convince payors to increase coverage for Galleri," without explaining any details about how this apparent end run around clinical studies would purportedly work.

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should

be disregarded. Therefore, this Court should disregard the proposed finding.

1396. Dr. Febbo also testified that while GRAIL's engagement with NHS in the United Kingdom is important, it does not demonstrate that GRAIL can expand internationally just as easily without Illumina: Dr. Febbo explained that the United Kingdom is particularly forward-thinking with genomics, and in Illumina's experience, success there does not automatically lead to success in other countries. (Febbo (Illumina) Tr. 4354–55.)

Response to Finding No. 1396

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is vague and against the weight of the evidence.

Respondents' counsel's out-of-context summary mischaracterizes and does not accurately represent Dr. Febbo's testimony.

The proposed finding is vague because it does not define "important" or "forward-thinking with genomics." Further, the proposed finding relies solely upon the self-serving testimony of Illumina's Chief Medical Officer Phil Febbo as evidence that GRAIL could not expand internationally just as easily without Illumina.

The proposed finding is misleading and against the weight of substantial evidence to the extent [redacted] Therefore, this Court should disregard the proposed finding.

1397. *Efficiencies and the Firewall.* Dr. Febbo testified that the firewall provisions in the Open Offer would not impede Illumina from achieving the efficiencies he testified about because the regulatory, market access and R&D efficiencies are "not dependent at all on having any knowledge about what other customers are doing in screening or what GRAIL's commercial success is"; none of the teams that report to him have access to confidential information of

Illumina's oncology customers and Illumina is not involved in the single-site PMA applications of its customers, nor does the FDA seek information from Illumina in connection with the review of a third party's single-site PMA application for tests running on Illumina instruments. (Febbo (Illumina) Tr. 4363–64.)

Response to Finding No. 1397

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is against the weight of the evidence and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by mixing in direct quotes with Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding is against the weight of the evidence showing that no firewall can prevent disclosure of competitively sensitive material. [redacted]

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

1398. *The Efficiencies Are Merger-Specific*. Dr. Febbo testified that based on his time and experience and Illumina GRAIL could not achieve the acceleration benefits he described by hiring FDA consultants because a company needs an internal core team that has experience with the authorities and there is "just not a deep, rich bench of experience available for consultants, and the model of a consultant driving [the regulatory submission process] just doesn't work as effectively as having internal employees." (Febbo (Illumina) Tr. 4365.)

Response to Finding No. 1398

Complaint Counsel objects to the proposed finding because it lacks foundation, mischaracterizes testimony, and is misleading, against the weight of the evidence, and speculative.

The proposed finding lacks foundation because Dr. Febbo does not have personal

knowledge regarding GRAIL's FDA experience.

The proposed finding mischaracterizes Dr. Febbo's testimony by mixing in direct quotes with Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding is vague as to what a "deep, rich bench of experience" means.

The proposed finding is misleading and against the weight of substantial evidence to the extent [redacted]

Cross-examination of Dr. Febbo revealed that his views on the ability of Illumina to accelerate FDA approval are merely vague speculation lacking personal knowledge. For example, [redacted]

[redacted] Moreover, Dr. Febbo testified at trial that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45).

The proposed finding is against the weight of the evidence showing Illumina's FDA experience is lacking. The number of class III PMA approvals that Illumina holds for NGS-based diagnostic tests can be counted on one finger. The Praxis therapy selection test is Illumina's only an NGS-based diagnostic test with a class III PMA approval. (Febbo (Illumina) Tr. 4445-46). But the Praxis test differs significantly from an MCED test—the Praxis test sequences tumor tissue; it is not a liquid biopsy test; and it does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446). Moreover, [redacted] Illumina's Praxis test received its PMA from the FDA before Dr. Febbo joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451). Since Dr. Febbo joined Illumina in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51). Since Dr. Febbo joined the company in 2018, Illumina has not even submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451). Moreover, [redacted] Illumina has never engaged with the FDA regarding an MCED test. (Febbo (Illumina) Tr. 4451).

The proposed finding is also against the weight of the evidence showing that [redacted]

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded.

1399. Dr. Febbo also testified that GRAIL could not just hire Illumina's regulatory and market access personnel because Illumina has taken a cross-functional, multidisciplinary approach, creating a "critical mass that have worked over the years to generate this institutional insight that is not dependent on any single employee." (Febbo (Illumina) Tr. 4366.)

Response to Finding No. 1399

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is vague, misleading, against the weight of the evidence, and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by mixing in direct quotes with Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding is vague as to what "cross-functional, multidisciplinary approach" means in that it does not explain who too this approach, why, for what purpose, and to what result. It is also vague because it does not define "critical mass" or explain what "over the years"

"institutional insight" refer to.

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest [redacted]

Cross-examination of Dr. Febbo revealed that his views on the ability of Illumina to accelerate FDA approval are merely vague speculation lacking personal knowledge. For example, [redacted] Moreover, Dr. Febbo testified at trial that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr.

4344-45).

The proposed finding is against the weight of the evidence showing Illumina's FDA experience is lacking. The number of class III PMA approvals that Illumina holds for NGS-based diagnostic tests can be counted on one finger. The Praxis therapy selection test is Illumina's only an NGS-based diagnostic test with a class III PMA approval. (Febbo (Illumina) Tr. 4445-46). But the Praxis test differs significantly from an MCED test—the Praxis test sequences tumor tissue; it is not a liquid biopsy test; and it does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446). Moreover, Illumina was not even the sponsor of the clinical study that the FDA relied on to grant PMA approval for Praxis. (CCFF ¶ 5169). Illumina's Praxis test received its PMA from the FDA before Dr. Febbo joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451). Since Dr. Febbo joined Illumina in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51). Since Dr. Febbo joined the company in 2018, Illumina has not even submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451). Moreover, [redacted] Illumina has never engaged with the FDA regarding an MCED test. (Febbo (Illumina) Tr. 4451).

The proposed finding is also against the weight of the evidence showing that [redacted]

[redacted]

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded.

1400. Dr. Febbo explained that Illumina and GRAIL could not achieve the efficiencies that the merger will create via contract, because with partnerships, "you don't see total alignment between two companies . . . nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships." (Febbo (Illumina) Tr. 4369.)

Response to Finding No. 1400

Complaint Counsel objects to the proposed finding because it is vague, misleading, against the weight of the evidence, and inherently speculative.

The proposed finding is vague as to what "total alignment between two companies," "depth of understanding of the processes," or "special sauce" refers to as no examples or context are given. It is also vague and unclear what "a lot of these companies," "layer of engagement," or "full realization" means.

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest [redacted]

[redacted]

Cross-examination of Dr. Febbo revealed that his views on the ability of Illumina to accelerate FDA approval are merely vague speculation lacking personal knowledge. For example, [redacted] Moreover, Dr. Febbo testified at trial that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45).

The proposed finding is against the weight of the evidence showing Illumina's FDA experience is lacking. The number of class III PMA approvals that Illumina holds for NGS-based diagnostic tests can be counted on one finger. The Praxis therapy selection test is Illumina's only an NGS-based diagnostic test with a class III PMA approval. (Febbo (Illumina)

Tr. 4445-46). But the Praxis test differs significantly from an MCED test—the Praxis test sequences tumor tissue; it is not a liquid biopsy test; and it does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446). Moreover, Illumina was not even the sponsor of the clinical study that the FDA relied on to grant PMA approval for Praxis. (CCFF ¶ 5169). Illumina's Praxis test received its PMA from the FDA before Dr. Febbo joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451). Since Dr. Febbo joined Illumina in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51). Since Dr. Febbo joined the company in 2018, Illumina has not even submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451). Moreover,

[redacted] Illumina has never engaged with the FDA regarding an MCED test. (Febbo (Illumina) Tr. 4451).

The proposed finding is also against the weight of the evidence showing that [redacted]

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course

documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded.

1401. Dr. Febbo testified that Illumina needs access to GRAIL's proprietary "secret sauce" to achieve the efficiencies of the Transaction; in terms of R&D efficiencies, "without understanding in depth the specifics of the sequencing that's performed, the specifics of the bioinformatics that goes from that sequencing and pulls out the methylation patterns [and] the machine-learning that's used to identify that cancer detection signal, to identify that tissue of origin of signal . . . it's almost impossible for our scientists, who know the technology better than any other company, to realize efficiencies"; in terms of regulatory efficiencies, Dr. Febbo testified that Illumina needs to have a deep assessment of GRAIL's full regulatory filings and all of its communications with FDA in order to engage with GRAIL, identify gaps based on Illumina's experience with FDA, so that they can "supplement those gaps, mitigate those risks, and find a path to acceleration." (Febbo (Illumina) Tr. 4369–71.)

Response to Finding No. 1401

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony, lacks foundation, and is vague, confusing, misleading, against the weight of the evidence, and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by mixing in direct quotes with Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding lacks foundation or support for the claim that Illumina's scientists "know the technology better than any other company." Dr. Febbo is not positioned to know in any meaningful way what scientific knowledge other companies possess.

The proposed finding is vague as to what is meant by "proprietary secret sauce" and "efficiencies of the Transaction." The proposed finding is vague in that no context or examples are given for "the specifics of the sequencing that's performed" and "the specifics of the bioinformatics."

The proposed finding is confusing in that it admits Illumina has not yet engaged with

GRAIL to identify gaps in GRAIL's regulatory filings, and thus has not identified any such gaps to date, but claims that Illumina nevertheless knows "can supplement those [unidentified] gaps" and "mitigate those [unidentified] risks."

The proposed finding is misleading and against the weight of substantial evidence to the extent Respondents suggest [redacted]

Cross-examination of Dr. Febbo revealed that his views on the ability of Illumina to accelerate FDA approval are merely vague speculation lacking personal knowledge. For example, [redacted] Moreover, Dr. Febbo testified at trial that Illumina will not

be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45).

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded.

1402. Alleged Foreclosure. Dr. Febbo testified to facts that debunk Complaint Counsel's theory of alleged foreclosure:

Response to Finding No. 1402

Complaint Counsel objects to the proposed finding because it is an incomplete sentence, it is conclusory, and it cites no evidence or source. Therefore, this Court should disregard the proposed finding.

1403. The Transaction would not give Illumina an incentive to impede innovation in cancer screening test development because cancer screening represents a major market opportunity and will be a highly competitive landscape, and Illumina has a great incentive to be the platform of choice for any company interested in developing a cancer screening test (Febbo (Illumina) Tr. 4330); "it is in [Illumina's] best interest to make sure that we continue to create an environment where laboratories are excited to use our platform to develop screening tests for cancer, as well as all the other applications we see happening" (Febbo (Illumina) Tr. 4331); sequencing will play an important clinical role in other areas of medicine, such as cardiovascular, metabolic, neurologic and inflammatory diseases, and if Illumina behaved in a way that disincentivized companies from using Illumina's platform in cancer screening, that would disincentivize other companies and laboratories from performing the early R&D work in those other areas on Illumina platforms (Febbo (Illumina) Tr. 4331).

Response to Finding No. 1403

Complaint Counsel objects to the proposed finding because it mischaracterizes testimony and is vague, against the weight of the evidence, and inherently speculative.

The proposed finding mischaracterizes Dr. Febbo's testimony by mixing in direct quotes

with Respondents' counsel's out-of-context paraphrased summary that does not accurately represent the testimony.

The proposed finding is vague because it does not define, quantify, or give any context to "major market opportunity." It is also vague because it is unclear what "highly competitive landscape" or "great incentive" refer to. The proposed finding is also vague because it does not identify "all the other applications we see happening" referenced. The proposed finding is vague because it does not explain what "behaved in a way that disincentivized other companies and laboratories" refers to or provide any context or examples.

The weight of the evidence shows that Illumina's reputation among its customers is already poor. [redacted]

Illumina does not need to care about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted]

[redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

For support for the proposed finding Respondents cite only to the unfounded, self-serving testimony of Illumina executive Dr. Febbo that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Dr. Febbo's base conjecture, this proposed finding of fact should be disregarded.

5. **Joydeep Goswami**

a. Background

1404. Joydeep Goswami is the chief strategy and corporate development officer at Illumina. (Goswami (Illumina) Tr. 3181.)

Response to Finding No. 1404

Complaint Counsel has no specific response to this proposed finding.

1405. Dr. Goswami joined Illumina in late September 2019. (Goswami (Illumina) Tr. 3183.) Dr. Goswami reports to Illumina's CEO, Francis deSouza, and his responsibilities include helping formulate the company's annual five-year strategic plan, overseeing key strategic projects undertaken by the company, involvement with mergers and acquisitions and business development. (Goswami (Illumina) Tr. 3181–84.) With respect to business development, Dr. Goswami is involved with Illumina's licensing business and partnerships, including pharmaceutical partnerships with companies and academic institutions for companion diagnostics, research and development and in vitro diagnostic ("IVD") agreements. (Goswami (Illumina) Tr. 3183–85.)

Response to Finding No. 1405

This proposed finding is vague insofar it does not explain with more particularity what is meant by "overseeing key strategic projects" or "involvement" with mergers and acquisition, business development, and licensing business and partnerships. [redacted] Dr. Goswami is also not familiar with technical aspects of Illumina's NGS platforms and described himself has having only a "high-level" understanding of the sequencers not the "technical intricacies." (PX7064 Goswami (Illumina) IHT at 70-71). Dr. Goswami also has no oversight over any of Illumina's regulatory strategies, and little knowledge of the FDA regulatory process, and no knowledge or experience relating to obtaining commercial or government reimbursement. (PX7064 Goswami (Illumina) IHT at 72, 165-66, 212).

Therefore, this Court should disregard the proposed finding.

1406. Prior to joining Illumina, Dr. Goswami worked with next generation sequencing platforms and genomic tests for approximately sixteen years for Thermo Fisher directly or companies who were later acquired by Thermo Fisher. (Goswami (Illumina) Tr. 3181–82.)

Response to Finding No. 1406

This proposed finding is vague insofar as Respondents do not elaborate what is meant by "worked with" next generation sequencing platforms, or what type of "genomic tests" encompassed Dr. Goswami's responsibilities. Therefore, this Court should disregard the proposed finding.

1407. Dr. Goswami has a Ph.D. in chemical and biochemical engineering and an M.B.A. (Goswami (Illumina) Tr. 3183.)

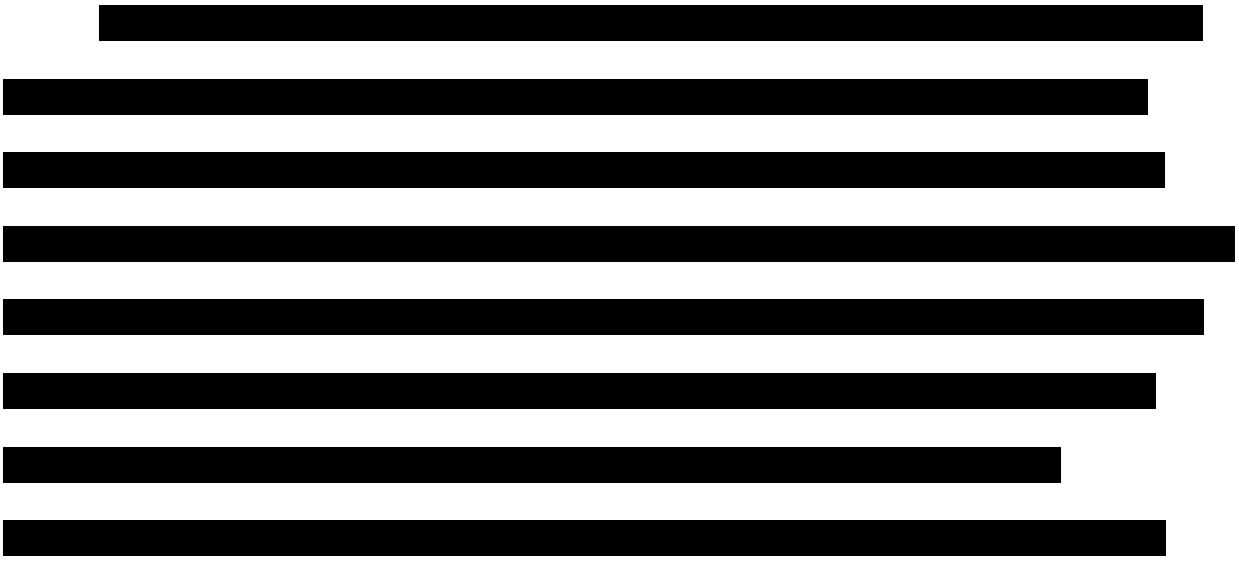
Response to Finding No. 1407

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1408. Background on IVD Distributed Tests or IVD Kits. Dr. Goswami testified that if a company wants to introduce a clinical test, the company can provide the test as a Laboratory Developed Test ("LDT"), a single-site Pre-Market Approval ("PMA") or single-site IVD test, or an IVD distributed kit. (Goswami (Illumina) Tr. 3185–87.)

Response to Finding No. 1408



[redacted]

1409. LDTs are the most common offering and involves a company clinically and analytically validating the test and then running the test in a single laboratory that has received CLIA/CAP certification. (Goswami (Illumina) Tr. 3185, 3195–96.)

Response to Finding No. 1409

[redacted]

[redacted]

1410. A single-site PMA test is run in a single lab, but the test has been clinically and analytically validated under the FDA's PMA regulations. (Goswami (Illumina) Tr. 3186.)

Response to Finding No. 1410

This proposed finding is vague by not describing in further detail what is meant by "clinically and analytically validated" nor explaining "PMA regulations." Therefore, this Court should disregard the proposed finding.

1411. An IVD distributed test or IVD kit involves a kit that is developed and manufactured by a test manufacturer and after receiving FDA approval, the test can be run in various labs provided that the labs are CLIA/CAP certified (Goswami (Illumina) Tr. 3186–87); the manufacturer of an IVD distributed test, not the lab running the test, bears the burden of continuing to manufacture the test, distributing the test and supporting the test in accordance with FDA guidelines (Goswami (Illumina) Tr. 3187).

Response to Finding No. 1411

This proposed finding is vague by not defining what is meant by "running the test" or "supporting the test in accordance with FDA guidelines. Therefore, this Court should disregard the proposed finding.

1412. Dr. Goswami pointed out that an IVD kit offering is rare and due to the burdens associated with IVD kits and test developers often choose to stay with an LDT model as opposed to seeking to provide an IVD kit; for example, the longest available molecular test, the BRCA test, was introduced in the 1990s and has never been offered as an IVD kit—neither has Exact Sciences' Cologuard test. (Goswami (Illumina) Tr. 3196.)

Response to Finding No. 1412

[redacted]

[redacted]

[redacted]

1413. Alleged Foreclosure. Dr. Goswami provided testimony that debunked Complaint Counsel's foreclosure theories, including that Illumina has a minimal role in providing support to test developers developing an LDT, IVD or IVD kitted test; the use of IVD kitted tests in the U.S. is rare; Illumina receives little information from a test developer developing a kitted test and what information it does receive is kept confidential; Illumina has provided IVD rights to test developers in therapy selection where it is vertically integrated. (Goswami (Illumina) Tr. 3187–89.)

Response to Finding No. 1413

[redacted]

[redacted]

[redacted]

1414. *Test Developers Do Not Need Support from Illumina.* Dr. Goswami testified that where a test developer utilizes an Illumina sequencing platform for an LDT or single-site IVD test, Illumina has a "very minimal role" of providing instruments and reagents and the test developer has the sole responsibility of developing, designing, qualifying and maintaining quality control of the test. (Goswami (Illumina) Tr. 3187–88.) Illumina's role is "mostly as a supplier". (Goswami (Illumina) Tr. 3188.)

Response to Finding No. 1414

Complaint Counsel objects to this proposed finding because it is vague, self-serving, unsupported and Dr. Goswami lacks any foundation to testify about the requirements of MCED test developers.

The proposed finding is vague because it is unclear what is meant by Illumina's "very minimal role" as "mostly as a supplier." This proposed finding is also self-serving and

unsupported to the extent that Respondents seek to rely solely on Dr. Joydeep Goswami, Illumina's SVP of Corporate Development and Strategic Planning, to speculate about what MCED test developers require from Illumina to develop and commercialize their tests. Respondents provide no additional evidence from third party witnesses or documents to support this proposed finding. Complaint Counsel also objects to this proposed finding because Dr. Goswami lacks any foundation to testify about what kind and degree of service and support MCED test developers require from Illumina. [redacted] Therefore, this Court should disregard the proposed finding.

1415. Dr. Goswami explained that Illumina also has a minimal role in IVD kit development: Illumina provides a Dx platform, is responsible for FDA approval of that Dx platform and provides a local run module ("LRM"), which is a software module Illumina transfers to the test developer to use with the test; the developer maintains responsibility for conducting the clinical trials, analytically and clinically validating the test for FDA approval and manufacturing and distributing the test kit in accordance with FDA guidelines (Goswami (Illumina) Tr. 3188–91).

Response to Finding No. 1415

This proposed finding is vague, confusing, self-serving and contrary to the weight of the evidence.

The proposed finding is vague because it is unclear what is meant by Illumina's "minimal role." This proposed finding is also confusing because it internally inconsistent. Respondents state that Illumina has a "minimal role" but then enumerates several important ways an IVD kit developer must rely on Illumina. Dr. Goswami lacks any foundation to offer testimony

dismissing the importance of the support that Illumina admits it must provide to an IVD kit developer. The weight of the evidence [redacted] Speculative, unreliable, and self-serving testimony from Illumina's own executives should not be credited over evidence from MCED test developers about their critical reliance on Illumina to develop and commercialize their tests. Therefore, this Court should disregard the proposed finding.

1416. *IVD Kit Tests Are Rare in the United States.* Dr. Goswami testified that it was rare for a test developer to seek an IVD kitted test; that IVD kits are most suitable for tests that have precious samples, present shipping challenges and require fast turnaround times and that early cancer screening is not one of these types of tests. (Goswami (Illumina) Tr. 3196–3200.)

Response to Finding No. 1416

[redacted]

[redacted]

1417. Dr. Goswami also testified that GRAIL has not expressed any intent to pursue a distributed IVD kit. (Goswami (Illumina) Tr. 3273.)

Response to Finding No. 1417

This proposed finding is unreliable and unsupported to the extent Respondents seek to rely on Dr. Joydeep Goswami, Illumina's SVP of Corporate Development and Strategic Planning, to provide evidentiary support for the GRAIL's purported lack of intent to pursue a distributed IVD kit. Therefore, this Court should disregard the proposed finding.

1418. *IVD Kit Test Developers Do Not Provide Illumina With Proprietary Information and That Information Is Kept Confidential.* Dr. Goswami testified that Illumina has no ability to disadvantage its IVD partners because customers who enter IVD agreements with Illumina do not share any proprietary information with Illumina; the information shared with Illumina is

limited to: the geographic location of the distribution and the timing of launch and FDA submission to ensure products are timely delivered and support is available, (Goswami (Illumina) Tr. 3219–20, 3227); and the size of the panel of the test, (Goswami (Illumina) Tr. 3226).

Response to Finding No. 1418

This proposed finding is confusing because it is facially contradictory. The proposed finding states that customers who enter into IVD agreements with Illumina "do not share any proprietary information with Illumina" but then identifies proprietary information IVD customers share with Illumina such as "the timing of launch and FDA submission." This proposed finding is also incomplete in that Dr. Goswami, as well as other Illumina executives testified that Illumina has access to other proprietary information from IVD developers such as sales volumes. (Goswami (Illumina) Tr. 3272 (testifying that customers provide Illumina with volume information so that "Illumina can provide the right level of support and inventory); *see also* CCFF ¶¶ 3002-06 (highlighting testimony from other Illumina executives about proprietary information customers share with Illumina). [redacted]

Additionally, this proposed finding is unreliable and unsupported to the extent that Respondents seek to rely solely on Dr. Joydeep Goswami, Illumina's SVP of Corporate Development and Strategic Planning, to speculate about the competitive significance of the timing of FDA submission, commercial launch, and purchasing volumes to MCED test developers. Respondents provide no evidentiary support beyond Dr. Goswami's self-serving testimony that Illumina "[keeps] confidential" this proprietary information, nor do Respondents describe with any particularity how Illumina keeps competitively sensitive information confidential. Moreover, this is against the weight of the evidence. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1419. Dr. Goswami noted that for the information test developers provide to Illumina related to IVD kit development: Illumina's agreements contain confidentiality provisions to protect the shared information; Illumina employees are required to sign separate agreements to commit to protect customer's sensitive information; Illumina maintains a separation among teams working with customers who have similar products; limitations are placed on the information shared with employees and upper management, including restrictions on sharing of documents with sensitive customer information; and employees consult with Illumina's legal team on what information may be shared with specific Illumina employees. (Goswami (Illumina) Tr. 3328–31.)

Response to Finding No. 1419

This proposed finding is self-serving, unreliable, and misleading.

Respondents are asking this Court to rely upon self-serving and unreliable testimony from an Illumina executive as evidence that Illumina refrains from acting in its own economic interest. First, the fact that Illumina follows these internal practices with IVD kit development customers demonstrates awareness that an IVD customer provides Illumina with competitively sensitive information and that customer might be concerned with sharing that information with Illumina.

It is also contrary to the weight of the evidence and misleading to imply that the purported "protections" described above are remotely sufficient to prevent Illumina from prioritizing its own assays over its competitors' assays. Illumina's former VP of Business Development admitted that when negotiating key agreements with its therapy selection (IVD) customers, "[w]e considered a term called 'cannibalization' – in other words, what would be the sales of TSO-500 [Illumina's therapy selection test] in the absence of these partners versus the presence of these partners – to try to decide at least a framework for summing up what the value

of that partnership should be." (Leite (Illumina) Tr. 2084-85). [redacted] Illumina's past history with IVD customers undermines Dr. Goswami's self-serving promises that these internal Illumina procedures are remotely sufficient to protect future IVD customers. Therefore, this Court should disregard the proposed finding.

1420. [redacted]

Response to Finding No. 1420

[redacted]

[redacted]

1421. Illumina's intent in entering IVD agreements is to lower the cost of kitted oncology assays in order to make the kits more widely available and spur innovation by allowing customers to rely on Illumina's platforms and infrastructure instead of spending the time and money required to develop their own. (Goswami (Illumina) Tr. 3217–18.)

Response to Finding No. 1421

This proposed finding is unreliable, self-serving, and misleading.

This proposed finding is unreliable and self-serving testimony from Illumina's own executive and not corroborated by any contemporaneous business documents. It is also a completely misleading statement that ignores Illumina's incentives when Illumina offers a competing product. The evidentiary record demonstrates Illumina's incentives when negotiating agreements with customers who offer products that compete with an Illumina offering. Illumina's former VP of Business Development admitted that when negotiating key agreements with its therapy selection customers, "[w]e considered a term called 'cannibalization' – in other words, what would be the sales of TSO-500 [Illumina's therapy selection test] in the absence of these partners versus the presence of these partners – to try to decide at least a framework for summing up what the value of that partnership should be." (Leite (Illumina) Tr. 2084-85).

[redacted]

This evidence of past behavior does not suggest that Illumina is motived by a benign intent "to lower the cost of kitted oncology assays in order to make the kits more widely available and spur

innovation."

This Court should not rely on unreliable, self-serving testimony from Illumina's own executives that provide empty promises of "intent" as assurance that Illumina will treat all customers neutrally in the future. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, Illumina can be expected to operate in its own economic interest in the future, just as it has done so in the past, notwithstanding empty promises from its own executives. This Court should disregard the proposed finding.

1422. Illumina supports the development of IVD kits on Illumina's sequencing platforms regardless of whether the test developer is seeking to develop an IVD kit for a test that competes with a test Illumina offers, (Goswami (Illumina) Tr. 3202–03) and because: it aligns with Illumina's missions to NGS available to a broad swath of customers who can develop solutions to help human health and economically genomic testing customers are more apt to adopt an FDA approved diagnostic platform. (Goswami (Illumina) Tr. 3201–02.)

Response to Finding No. 1422

This proposed finding is unreliable, self-serving, and misleading.

This proposed finding is unreliable and self-serving testimony from Illumina's own executive and not corroborated by any contemporaneous business documents. It is also a completely misleading statement that ignores Illumina's economic incentives when Illumina offers a downstream product that competes with a customer's product that is reliant on Illumina's sequencers. This Court should not rely on unreliable, self-serving testimony from Illumina's

own executives that provide empty promises that Illumina "supports" its customers because "it aligns with Illumina's missions to [make] NGS available to a broad swath of customers who can develop solutions to help human health" as assurance that Illumina will treat all customers neutrally in the future. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, Illumina can be expected to operate in its own economic interest in the future, just as it has done so in the past, notwithstanding empty promises from its own executives. This Court should disregard the proposed finding.

1423. [redacted]

Response to Finding No. 1423

[redacted]

[redacted]

[redacted]

1424. [redacted]

Response to Finding No. 1424

[redacted]

[redacted]

1425. Dr. Goswami pointed out that not all platform providers support IVD kit development on their platforms. (Goswami (Illumina) Tr. 3202.)

Response to Finding No. 1425

This proposed founding is vague, lacks foundation, and is misleading. This proposed finding is vague because respondents don't identify which companies don't support IVD kit development. This proposed finding is also misleading [redacted]. Lastly, Dr. Goswami has no basis to opine on the business or strategy plans of other platform providers nor their reasons for choosing a business model. Therefore, this Court should disregard the proposed finding.

1426. Open Offer IVD Terms and Related Provisions. Dr. Goswami testified that any alleged foreclosure related to IVD Kits is impossible due to the terms of the Open Offer. (Goswami (Illumina) Tr. 3207–35.)

Response to Finding No. 1426

[redacted]

[redacted]

1427. Illumina's Open Offer commits Illumina to assisting customers, including MCED test developers, who want to develop IVD kits and allows customers to enter an IVD agreement with Illumina at any time from the close of the Transaction until six years after the close of the Transaction. (Goswami (Illumina) Tr. 3207, 3234–35.)

Response to Finding No. 1427

[redacted]

[redacted]

[redacted]

1428. The IVD terms of the Open Offer are available to oncology test developers who want to enter into an IVD agreement with Illumina and provides test developers with the power to select the terms and platform it would utilize and begin negotiations with Illumina with the Open Offer terms as a floor of what is available. (Goswami (Illumina) Tr. 3204–06, 3208.)

Response to Finding No. 1428

[redacted]

[redacted]

1429. The IVD provisions of the Open Offer are based on prior IVD agreements between Illumina and test developers (Goswami (Illumina) Tr. 3206) and are intended to provide clarity to Illumina's oncology customers, address concerns with the transaction raised by Complaint Counsel and ensure an even playing filed for all of Illumina's oncology customers (Goswami (Illumina) Tr. 3206–07).

Response to Finding No. 1429

[redacted]

[redacted]

[redacted]

1430. The IVD provisions of the Open Offer: limit development of IVD kits to three different tests, but do not place a cap on the number of IVD kits for a particular test a customer can offer, which terms are in accordance with Illumina's prior IVD agreements, (Goswami (Illumina) Tr. 3208–09); allow for IVD kit distribution in any geographic area in which Illumina's sequencers have approval for IVD usage, (Goswami (Illumina) Tr. 3209–10); and ten-year term for IVD agreements related to the NextSeq and NovaSeq platforms and for all-platform agreements the term is fifteen years, (Goswami (Illumina) Tr. 3210).

Response to Finding No. 1430

This proposed finding is vague and confusing as to what is meant by "all-platform

agreements" as Respondents do not provide any clarity as to the type of platforms this 15 year term would apply to. [redacted] It is difficult to predict all of the situations that might arise over the next ten to fifteen years. [redacted] Therefore, this Court should disregard the proposed finding.

1431. The Open Offer's IVD provisions commit Illumina to maintaining the diagnostic platforms for the length of the IVD agreements. (Goswami (Illumina) Tr. 3211–12.)

Response to Finding No. 1431

This proposed finding is vague because it does not describe what is meant by "maintaining" the diagnostic platforms. This proposed finding is misleading to the extent it implies customers will be able to know what services Illumina is providing to Grail and other Illumina customers. [redacted] Mr. George, Invitae's

CEO, testified that under Open Offer term 4(a) it is "not clear" how Invitae will know they are receiving access to the same product services and support services as GRAIL. (PX7081 (George (Invitae) Dep. at 93-94)).

Even Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71) (testifying that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.")). [redacted] Therefore, this Court should disregard the proposed finding.

1432. The financial terms of the IVD provisions of the Open Offer are fairly standard in Illumina's industry and include the technology access fee, milestone payments and revenue sharing terms (Goswami (Illumina) Tr. 3212) and the terms do not differ based on whether the test developer offers a test that competes with a test Illumina offers, (Goswami (Illumina) Tr. 3216).

Response to Finding No. 1432

[redacted]

[redacted]

[redacted]

1433. The technology access fee is an up-front payment of $25 million for all-platform development, which is based on: the fact that Illumina has to invest years and millions of dollars to develop diagnostic platforms and the investments are made at Illumina's risk as the FDA may not approve the platform and customers have not yet committed to adopt the diagnostic platform for IVD kit usage; and customer feedback on acceptable range of a technology access fee. (Goswami (Illumina) Tr. 3213–14.)

Response to Finding No. 1433

[redacted]

[redacted]

1434. Customers who do not want an all-platform agreement for IVD kits have the option of entering an agreement specific to NovaSeq or NextSeq platforms that have technology access fees of $15 million and $3 million, respectively. (Goswami (Illumina) Tr. 3214-15.)

Response to Finding No. 1434

[redacted]

[redacted]

1435. The revenue share term is due after a test developer commercially launches an IVD kit, (Goswami (Illumina) Tr. 3212); the revenue share is a six percent, which falls between the four and ten percent revenue share term that is fairly common in the life sciences and diagnostics industries, (Goswami (Illumina) Tr. 3215); and Illumina arrived at the six percent figure after discussing with customers to obtain their views on an acceptable revenue share term, (Goswami (Illumina) Tr. 3215.)

Response to Finding No. 1435

[redacted]

[redacted]

[redacted]

1436. The milestone payments are due when a test developer reaches certain stages of development of an IVD kit, which prevents the test developer from making payments before achieving certain significant progress on developing an IVD kit, (Goswami (Illumina) Tr. 3212, 3215–16); and Illumina arrived at the milestone payment figures after considering the infrastructure and maintenance investments related to optimizing platforms for usage with IVD kits and discussions with customers on fair figures, (Goswami (Illumina) Tr. 3216).

Response to Finding No. 1436

[redacted]

[redacted]

1437. Other Open Offer Provisions. The Open Offer contains a firewall provision to assure customers that Illumina will not directly allow GRAIL personnel or Illumina employees, including upper-level executives of both GRAIL and Illumina, who interact with GRAIL to access confidential information of Illumina's customers who provide offerings similar to GRAIL's offerings. (Goswami (Illumina) Tr. 3231–32.)

Response to Finding No. 1437

[redacted]

[redacted]

1438. Illumina has codified procedures to discipline Illumina employees for sharing confidential information with GRAIL employees. (Goswami (Illumina) Tr. 3232–33.)

Response to Finding No. 1438

[redacted]

[redacted]

1439. The audit provisions of the Open Offer are designed to identify any breaches of confidentiality that Illumina's internal controls do not detect. (Goswami (Illumina) Tr. 3233.)

Response to Finding No. 1439

[redacted]

[redacted]

1440. Notification requirements in the Open Offer require Illumina to promptly notify the customer if Illumina becomes aware that of a breach of confidentiality concerning the customer's confidential information either via an audit or Illumina's internal procedures. (Goswami (Illumina) Tr. 3233.)

Response to Finding No. 1440

[redacted]

[redacted]

6. **Ammar Qadan**

a. Background

1441. Mr. Qadan is the Vice President and Global Head of Market Access at Illumina. He joined Illumina in November of 2016. (Qadan (Illumina) Tr. 4098–99, 4105.)

Response to Finding No. 1441

Complaint Counsel has no specific response to this proposed finding.

1442. As a team leader of the market access team, Qadan is responsible for understanding the unmet needs of the payor community. (Qadan (Illumina) Tr. 4105–06.) By understanding the needs of the payors, he and his team can develop the evidence necessary to deliver on those needs and communicate the outcomes through publications and other channels. (Qadan (Illumina) Tr. 4106.)

Response to Finding No. 1442

The proposed finding is vague and misleading. It is unclear what "unmet needs of the payor community" this finding is referring to. The finding is misleading to the extent that it implies that Mr. Qadan is qualified to speak to clinical uptake requirements of MCED tests. For example, Illumina has entered into only one risk-sharing agreement involving NIPT. (Qadan (Illumina) Tr. 4249). That agreement did not generate economic and clinical utility for Grail's Galleri test. (Qadan (Illumina) Tr. 4252). In fact, NIPT is not a good comparison for Galleri in terms of payer uptake and Galleri will require different types of evidence and studies because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59). For the reasons stated, the Court should disregard this finding.

1443. He has a bachelor's degree in pharmaceutical science from the University of Jordan in Amman, Jordan. (Qadan (Illumina) Tr. 4099.) Prior to joining Illumina, Mr. Qadan spent the majority of his career at Bristol-Myers Squibb and a short time at Halozyme Therapeutics. (Qadan (Illumina) Tr. 4099.)

Response to Finding No. 1443

Complaint Counsel has no specific response to this proposed finding.

1444. Mr. Qadan started his career at Bristol-Myers Squibb in July of 1990 and remained there for around 24 years. (Qadan (Illumina) Tr. 4099.) The market access activities Mr. Qadan was involved in at Bristol-Myers Squibb included coverage and reimbursement, marketing, initiatives for oncology drugs, diabetes payor marketing, and market access work on hepatitis C. (Qadan (Illumina) Tr. 4101–02.) In July of 2014 Mr. Qadan joined Halozyme Therapeutics, where he was the market access and value lead for their lead product for the treatment of pancreatic cancer, and later became the lead for the development and commercialization for that product. (Qadan (Illumina) Tr. 4103–04.)

Response to Finding No. 1444

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1445. Illumina's Market Access Capabilities. Mr. Qadan provided testimony about Illumina's market access function and explained that: the organization's goal is to increase coverage and reimbursement across clinical applications for genomics, which he measures by the number of lives covered globally by reimbursement authorities (Qadan (Illumina) Tr. 4110); the organization's functions include strategy and operations, health economics and outcomes research—which is the "power engine" of the organization that develops clinical and economic utility evidence—and payor relationships (Qadan (Illumina) Tr. 4109); and it is important for the market access team to work cross-functionally with other departments within Illumina in order to develop evidence of clinical and economic utility. (Qadan (Illumina) Tr. 4107–08.)

Response to Finding No. 1445

The proposed finding misstates Mr. Qadan's testimony. Mr. Qadan did not explain that the market access team's goal was to "increase coverage and reimbursement across clinical applications for genomics" generally, but rather just for the three clinical applications they are focused on (which does not include MCED testing). (Qadan (Illumina) Tr. 4110; 4121). The proposed finding is also misleading to the extent that it implies that Mr. Qadan has the foundation to speak to Illumina's work in other departments. For the reasons stated, the Court should disregard this finding.

1446. Mr. Qadan explained how and why Illumina's market access function came into existence and expanded thereafter: the function was created with his hire (Qadan (Illumina) Tr. 4112); Illumina created the function because reimbursement is critical to achieve wide-scale adoption for genomics in clinical practice (Qadan (Illumina) Tr. 4113); and Mr. Qadan was tasked with identifying the structure needed to develop the market access team and then to recruit people into roles around the globe. (Qadan (Illumina) Tr. 4113–14.)

Response to Finding No. 1446

Complaint Counsel has no specific response to this proposed finding.

1447. Mr. Qadan explained: that expanding the market access team was a "steep process" that took three to four years to get everything into a steady state (Qadan (Illumina) Tr. 4114); that building out the team required hiring those trained as health economists for the health outcomes and research roles, and experience working with payors for the payor partner team (Qadan (Illumina) Tr. 4114–15); that having expertise in genomics is an important quality, because building the case for clinical and economic utility is more complicated than it is in pharmaceuticals (Qadan (Illumina) Tr. 4115); and that it took him six to nine months and a steep learning curve to gain a detailed understanding of genomics. (Qadan (Illumina) Tr. 4115–16.)

Response to Finding No. 1447

The proposed finding is misleading to extent that it either implies a market access team needs to be staffed with employees with genomics experience to be effective, or that Illumina's own team is composed of only people with genomics experience. As Mr. Qadan admits, it only took him six to nine months (the same amount of time that has passed since this trial ended) to get up to speed in genomics despite having primarily pharmaceutical experience prior to joining Illumina. (Qadan (Illumina) Tr. 4115–16.) Consistently, Illumina's market access team of 13 is comprised of multiple employees that did not have prior genomics experience. For example, Siyang Peng came from Evidera – a contract research organization. (Qadan (Illumina) Tr. 4291). Daisey Du came from Medtronic – a healthcare technology company. (Qadan (Illumina) Tr. 4291). And Bela Bapat came from Cardinal Health. (Qadan (Illumina) Tr. 4291). For the reasons stated, the Court should disregard this finding.

1448. Mr. Qadan testified about the importance Illumina's reputation plays in shaping its ability to gain market access for genomic tests, explaining that: unlike most companies in genomics, which focus on one or two main applications, Illumina plays a broader role in the field, and since payors must deal with genomics in the same broader sense, it is important for Illumina to develop partnerships with payors (Qadan (Illumina) Tr. 4116–17); Illumina has improved its reputation with payors through its early projects with payors like Genomics England (Qadan (Illumina) Tr. 4117); based on the reputation Illumina has built in market access, it has become less and less difficult to find talented applicants when recruiting for new roles (Qadan (Illumina) Tr. 4117); and, based on his work and experience, it has taken Illumina three to four years to build this reputation in market access. (Qadan (Illumina) Tr. 4118.)

Response to Finding No. 1448

The proposed finding is unsupported, irrelevant, and misleading. In the first instance, Mr. Qadan does not have the foundation to speak to payer's views of Illumina's reputation. Illumina chose not to call any payers to testify regarding Illumina's reputation and cannot now substitute Mr. Qadan's biased testimony, unsupported by any documents or specific facts. The proposed finding should be disregarded on that basis alone. Further, the proposed finding is irrelevant to any fact at issue in this case. Specifically, Illumina's alleged reputation has no bearing as to Grail's market access capabilities. Finally, the proposed finding is misleading to the extent it implies that that Illumina's reputation with payers is better than Grail's. Mr. Qadan does not have the foundation to make that comparison. [redacted] For the reasons stated, the Court should disregard this finding.

1449. In addition to building the market access group's reputation, Mr. Qadan testified that he has overseen an increase in its budget: due to the expansion of clinical applications the group will cover; the expansion of Illumina's geographic footprint into the Middle East, Africa and Latin America; and the expansion of Illumina's evidence generation partnerships, Illumina's budget has increased from $3 million to $11 million annually, excluding headcount, during Mr. Qadan's tenure. (Qadan (Illumina) Tr. 4118–19.)

Response to Finding No. 1449

The proposed finding is irrelevant and misleading and should be disregarded. Illumina's market access budget is irrelevant to any fact at issue in this case, specifically, whether or how Illumina would be able to accelerate payer adoption of Galleri. Indeed as Mr. Qadan admitted, the market access team did not have the budget for any clinical utility studies focused on Galleri coverage and reimbursement. (PX7084 (Qadan (Illumina) Dep. at 83)). As such, the proposed finding is misleading to the extent it implies that Illumina can accelerate payer adoption. [redacted]

[redacted] For the reasons stated, the Court should disregard this finding.

1450. Mr. Qadan explained that so far, the market access group's focus has been on three particular clinical applications: noninvasive prenatal testing ("NIPT"), tumor comprehensive genomic profiling ("CGP") and whole genome sequencing in rare and undiagnosed genetic diseases ("RUGD"). (Qadan (Illumina) Tr. 4121.)

Response to Finding No. 1450

The proposed finding is misleading to the extent it implies that Illumina's alleged experience in NIPT, tumor comprehensive genomic profiling, and whole genomic sequencing is relevant to whether Illumina will be able to accelerate payer adoption of Galleri. For example, Illumina has entered into only one risk-sharing agreement involving NIPT. (Qadan (Illumina) Tr. 4249). That agreement did not generate economic and clinical utility for Grail's Galleri test. (Qadan (Illumina) Tr. 4252). In fact, NIPT is not a good comparison for Galleri in terms of payer uptake, and Galleri will require different types of evidence and studies because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59). [redacted] For the reasons stated, the Court should disregard this finding.

1451. *NIPT.* Mr. Qadan testified that Illumina's efforts to expand market access for NIPT have included building evidence of clinical and economic utility and working with health technology assessment agencies and single-payer systems outside the U.S. (Qadan (Illumina) Tr. 4122); previously, payors had only covered NIPT for high-risk pregnancies (defined as pregnant women above the age of 35) and what Illumina found was that there was little clinical or economic utility data for average-risk pregnancies. (Qadan (Illumina) Tr. 4122–23.)

Response to Finding No. 1451

The proposed finding is irrelevant. [redacted]

[redacted] Moreover, the evidence shows that Illumina's claims lack any validity. As Mr. Qadan admitted, Illumina has not discussed acceleration of Galleri with payers outside the United States nor has it analyzed or estimated how alleged international acceleration would impact payer coverage or market access in the United States. (Qadan (Illumina) Tr. 4277-78). For the reasons stated, the Court should disregard this finding.

1452. Mr. Qadan explained that Illumina signed a risk-sharing agreement with payor Harvard Pilgrim Health Care to help generate the clinical and economic utility data: Harvard Pilgrim would cover NIPT for all pregnancies and Illumina would help cover the cost as well as gather the evidence around what clinical utility was created as a result of that expansion and at what cost, with the intention of publishing the results. (Qadan (Illumina) Tr. 4123–24.)

Response to Finding No. 1452

The proposed finding is misleading to the extent that it implies Illumina has unique capabilities regarding payer acceleration due to its risk sharing agreement with Harvard Pilgrim. Rather, as Mr. Qadan admitted, Illumina did not invent risk-sharing agreements and, in fact, has only completed one risk-sharing agreement. (Qadan (Illumina) Tr. 4123). Moreover, Illumina did not design the Harvard Pilgrim risk-sharing agreement on its own but rather collaborated with the University of Colorado, who led part of the study design. (Qadan (Illumina) Tr. 4270). Finally, the proposed finding is misleading and against the weight of the evidence to the extent that it implies that Illumina's alleged experience with Harvard Pilgrim is relevant as to whether Illumina has the ability to accelerate the adoption of Galleri. As the evidence shows, Illumina's risk-sharing agreement with Harvard Pilgrim for a different product is irrelevant as to whether it can accelerate adoption of Galleri. Mr. Qadan admitted that agreement did not generate economic and clinical utility for Grail's Galleri test. (Qadan (Illumina) Tr. 4252). He also admitted that NIPT is not a good comparison for Galleri in terms of payer uptake and Galleri will require different types of evidence and studies because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59). [redacted] For the

reasons stated, the Court should disregard this finding.

1453. Mr. Qadan explained that the partnership was a success: *first,* Illumina and Harvard Pilgrim demonstrated that there is clinical utility of expanding the use of NIPT to average or lower-risk pregnancies by lowering the number of unnecessary invasive tests in that population (Qadan (Illumina) Tr. 4124); *second*, from an economic utility point of view, there was an increase in cost of only 2.6 cents per member per month, which is very low cost for any payor to absorb (Qadan (Illumina) Tr. 4124); and *third*, those who used NIPT did not duplicate testing with older methods that were used before in that population, such as traditional serum screening, which is less sensitive than NIPT. (Qadan (Illumina) Tr. 4124.)

Response to Finding No. 1453

The proposed finding is misleading, irrelevant and against the weight of the evidence to the extent that it implies that Illumina's alleged experience with Harvard Pilgrim is relevant as to whether Illumina has the ability to accelerate the adoption of Galleri. As the evidence shows, Illumina's risk-sharing agreement with Harvard Pilgrim for a different product is irrelevant as to whether it can accelerate adoption of Galleri. Mr. Qadan admitted that agreement did not generate economic and clinical utility for Grail's Galleri test. (Qadan (Illumina) Tr. 4252). He also admitted that NIPT is not a good comparison for Galleri in terms of payer uptake and Galleri will require different types of evidence and studies because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59). [redacted] For the reasons stated, the Court should disregard this finding.

1454. Mr. Qadan testified about the impact of publishing the results of this study: Illumina is using the economic utility findings in its discussions with Medicaid so that they can understand the budget impact of expanding NIPT in Medicaid pregnancies (Qadan (Illumina) Tr. 4125); following the study, the American College of Obstetricians and Gynecologists ("ACOG") changed their guidelines to recommend NIPT in all pregnancies (Qadan (Illumina) Tr. 4125); and Illumina shared the results of their Harvard Pilgrim work with some commercial payors, like UnitedHealthcare, such that, by the end of 2020, around an additional 55 million lives were covered by payors for NIPT in lower-risk pregnancies. (Qadan (Illumina) Tr. 4125–26.)

Response to Finding No. 1454

The proposed citing is unsupported, irrelevant, and misleading. The proposed finding's contention that the Harvard Pilgrim study alone caused ACOG to change their guidelines and

commercial payers to expand NIPT coverage is supported only by Mr. Qadan's biased testimony. Respondents provide no documents supporting this contention nor did they adduce any witnesses from either ACOG or an insurer to support their claims. Moreover, it is controverted by the weight of the evidence. Mr. Qadan admitted that Harvard Pilgrim was limited in scope to only "the New England" region. (Qadan (Illumina) Tr. 3164). [redacted] Moreover, Illumina admitted that other companies aside from Illumina have conducted clinical utility studies. (Qadan (Illumina) Tr. 4269). As such, the weight of the evidence shows that Illumina's limited study with Harvard Pilgrim cannot be solely responsible for any alleged uptake in payer coverage for NIPT.

As the evidence shows, Illumina's risk-sharing agreement with Harvard Pilgrim for a different product is irrelevant as to whether it can accelerate adoption of Galleri. Mr. Qadan admitted that agreement did not generate economic and clinical utility for Grail's Galleri test. (Qadan (Illumina) Tr. 4252). He also admitted that NIPT is not a good comparison for Galleri in terms of payer uptake and Galleri will require different types of evidence and studies because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59). [redacted] For the reasons stated, the Court should disregard this finding.

1455. After successfully convincing commercial payors to expand market access, Mr. Qadan testified that Illumina's work in NIPT still continues: in the U.S., Illumina's focus now is on Medicaid plans, specifically in California, Texas and New York, to reduce disparities in healthcare in that population (Qadan (Illumina) Tr. 4130); while internationally, Illumina continues to make submissions in a number of different countries and has been able to expand coverage over the past couple of years. (Qadan (Illumina) Tr. 4130–31.)

Response to Finding No. 1455

The proposed finding is vague because it is unclear what "submissions" or "countries"

the proposed finding refers to or how these supposed "submissions" expanded coverage. Moreover, the proposed finding is unsupported, irrelevant, and incorrect. The proposed finding is supported solely by Mr. Qadan's biased testimony and is unaccompanied by sufficient facts or any supporting documents. The proposed finding should be disregarded on that basis alone. Moreover, the proposed finding is irrelevant. [redacted] Moreover, the evidence shows that Illumina's claims lack any validity. As Mr. Qadan admitted, Illumina has not discussed acceleration of Galleri with payers outside the United States nor has it analyzed or estimated how alleged international acceleration would impact payer coverage or market access in the United States. (Qadan (Illumina) Tr. 4277-78). [redacted] For the reasons stated, the Court should disregard this finding.

1456. Mr. Qadan explained that Illumina's work to expand coverage of NIPT applies to all NIPT tests, not just Illumina's: if payors are convinced that they need to cover a test, they develop a medical policy that says NIPT is medically necessary, and that applies across the board at an application level. (Qadan (Illumina) Tr. 4131.)

Response to Finding No. 1456

The proposed finding is unsupported. Mr. Qadan does not have foundation to testify about payer's policies. Mr. Qadan has never worked at a commercial insurer. (Qadan (Illumina) Tr. 4287). Given the proposed finding is supported only by Mr. Qadan's biased, unfounded opinion, it should be disregarded on that basis alone. Moreover, this finding is also irrelevant to

the extent it is suggesting that Illumina's alleged experience in NIPT provides it the ability to accelerate payer adoption of Grail. Mr. Qadan also admitted that NIPT is not a good comparison for Galleri in terms of payer uptake and Galleri will require different types of evidence and studies because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59). [redacted] For this reason (and the reason already stated) the Court should disregard this finding.

1457. *CGP.* Mr. Qadan testified that Illumina's market access work has helped expand coverage of CGP: Illumina has developed partnerships with Providence Healthcare in the U.S., the Belgian Society of Oncology, the University of Melbourne in Australia, and in Japan, to develop clinical utility evidence that supports the use of tumor comprehensive genomic profiling instead of the standard of care today, which is single-gene tests and small genomic panels (Qadan (Illumina) Tr. 4132–33); and over the past two to three years, the number of patients globally who have been covered for tumor comprehensive genomic profiling has increased nearly sixfold. (Qadan (Illumina) Tr. 4133.)

Response to Finding No. 1457

The proposed finding is irrelevant and incorrect. [redacted] Moreover, the evidence shows that Illumina's claims lack any validity. As Mr. Qadan admitted, Illumina has not discussed acceleration of Galleri with payers outside the United States nor has it analyzed or estimated how alleged international acceleration would impact payer coverage or market access in the United States. (Qadan (Illumina) Tr. 4277-78). For the reasons stated, the Court should disregard this finding.

1458. *RUGD.* Mr. Qadan testified that Illumina's market access work has helped expand coverage of RUGD and has involved: partnering with Rady Children's Hospital in San Diego and other hospitals in the U.S., the California and Michigan state Medicaid systems and with countries and healthcare systems outside the U.S., including Genomics England, the State

of Queensland in Australia, Taiwan and Israel, in order to develop clinical and economic utility evidence for RUGD (Qadan (Illumina) Tr. 4135); spending significant time building an economic utility model demonstrating that whole genome sequencing of rare and undiagnosed genetic diseases could be cost-saving for healthcare systems, which is slated for publication in a peer-reviewed scientific journal (Qadan (Illumina) Tr. 4134–35); and entering risk-sharing agreements with Harvard Pilgrim Health Care to study real-world effects of coverage for whole genome sequencing and with the state of Queensland in Australia to study the economic and clinical utility of providing every child with undiagnosed genetic disease whole genome sequencing as a first-line test. (Qadan (Illumina) Tr. 4136–37.)

Response to Finding No. 1458

The proposed finding is irrelevant. Illumina's alleged ability to expand coverage of RUGD has no bearing on whether it will be able to similarly expand payer acceptance of Galleri. Moreover, the proposed finding is supported only by Mr. Qadan's biased statement. Mr. Qadan provides no detail beyond high-level, conclusory statements attributing all advancement of payer coverage for RUGD to Illumina's partnership with a few entities. Mr. Qadan's statement is not credible and, as the proposed finding is based solely on his assertion, the Court should disregard this finding.

1459. Mr. Qadan testified that in the past two to three years, Illumina's efforts have resulted in 36 million covered lives for whole genome sequencing in the U.S. and a fivefold increase overall. (Qadan (Illumina) Tr. 4137.)

Response to Finding No. 1459

The proposed finding is irrelevant. Illumina's alleged ability to expand coverage of RUGD has no bearing on whether it will be able to similarly expand payer acceptance of Galleri and should be disregarded. Moreover, the proposed finding is supported only by Mr. Qadan's biased statement. Mr. Qadan provides no detail beyond high-level, conclusory statements attributing all advancement of payer coverage for RUGD to Illumina's "efforts." Mr. Qadan's statement is not credible and, as the proposed finding is based solely on his assertion, the Court should disregard this finding.

1460. Mr. Qadan testified that across the 21 countries and three applications Illumina's market access team is focused on, they have secured more than one billion covered lives. (Qadan (Illumina) Tr. 4137–38.)

Response to Finding No. 1460

The proposed finding is vague, irrelevant, and unsupported. First, the proposed finding is vague given it is unclear how Respondents are alleging that "they have secured more than one billion lives" as well as the underlying source or analysis for that contention. Second, the proposed finding is supported only by Mr. Qadan's biased testimony. Respondents provide citations to no documents nor any analysis to show why Illumina's market access group should be credited with covering "one billion covered lives." Third, this finding is irrelevant. [redacted] Moreover, the evidence shows that Illumina's claims lack any validity. As Mr. Qadan admitted, Illumina has not discussed acceleration of Galleri with payers outside the United States nor has it analyzed or estimated how alleged international acceleration would impact payer coverage or market access in the United States. (Qadan (Illumina) Tr. 4277-78). Illumina's alleged experience in obtaining coverage for other applications is similarly not probative of its ability to accelerate coverage for Grail's Galleri test. For the reasons stated, the Court should disregard this finding.

1461. *Risk-Sharing Agreements*. Mr. Qadan explained generally how risk-sharing agreements work: a risk-sharing agreement is a form of value-based contract whereby the payment or the decision by the payor is tied to the value provided by the test (Qadan (Illumina) Tr. 4138); for instance, in Illumina's case with Harvard Pilgrim, in order to get clinical utility data, Illumina shared the economic risks associated with expanding coverage for NIPT by covering Harvard Pilgrim's increased costs up to a capped amount as Illumina developed the data, and allowing Harvard Pilgrim to carry the risk if that cap were exceeded. (Qadan (Illumina) Tr. 4138–39.)

Response to Finding No. 1461

The proposed finding is incorrect to the extent that it suggests that Illumina has unique experience in entering risk sharing agreements. In contrast, Mr. Qadan admitted that Illumina did not "invent" risk sharing agreements and, in fact, has only completed one risk-sharing agreement. (Qadan (Illumina) Tr. 4249). Moreover, other companies have also entered into risk sharing agreements. (Qadan (Illumina) Tr. 4269). The Court should disregard this proposed finding to the extent that it implies that Illumina has unique experience in entering risk-sharing agreements.

1462. Mr. Qadan testified that Illumina has entered into three risk-sharing agreements in total: the NIPT agreement with Harvard Pilgrim, a risk-sharing agreement with Harvard Pilgrim regarding whole genome sequencing and an agreement with the state of Queensland in Australia for whole genome sequencing. (Qadan (Illumina) Tr. 4140.)

Response to Finding No. 1462

The proposed finding is incorrect and misleading. The proposed finding is incorrect to the extent that it implies that Illumina has completed three risk-sharing agreements. Illumina has completed one. (Qadan (Illumina) Tr. 4249). The proposed finding is also misleading to the extent it implies that Illumina has a unique ability to enter into risk-sharing agreements. In contrast, Mr. Qadan admitted that Illumina did not "invent" risk sharing agreements and, in fact, has only completed one risk-sharing agreement. (Qadan (Illumina) Tr. 4249). Moreover, other companies have also entered into risk sharing agreements. (Qadan (Illumina) Tr. 4269). For the reasons stated, the Court should disregard this finding.

1463. Mr. Qadan testified: that to his knowledge, no manufacturer had entered into a risk-sharing agreement involving NGS prior to Illumina; that risk-sharing agreements are not common between manufacturers and payors or health systems, and are rather more common between payors and healthcare providers, because they are easier to administer; that when there are risk-sharing agreements involving a manufacturer, they typically involve pharmaceuticals, rather than genomics or diagnostics; that risk-sharing agreements are not common in diagnostics and genomics because the data associated with genomics is much more complicated than that of pharmaceuticals. (Qadan, (Illumina) Tr. 4140–43.)

Response to Finding No. 1463

The proposed finding is unsupported and misleading. Respondents only cite Mr. Qadan's biased testimony in support of this finding. Mr. Qadan has spent the majority of his career in the pharmaceutical industry and has not worked at a health system or other sequencing platform. (Qadan, (Illumina) Tr. 4287-88); [redacted]. Moreover, Mr. Qadan has only been involved in one risk-sharing agreement. (Qadan (Illumina) Tr. 4249). As such, Mr. Qadan does not have the foundation to testify regarding the frequency of risk-sharing agreements among companies other than Illumina. Given the proposed finding is only supported by Mr. Qadan's biased, unfounded opinion, the Court should disregard the proposed finding on that basis alone. The proposed finding is also misleading to the extent that it implies that Illumina's experience with its NIPT risk-sharing agreement is unique. In contrast, Mr. Qadan admitted that Illumina did not "invent" risk sharing agreements and, other companies have also entered into risk sharing agreements. (Qadan (Illumina) Tr. 4269). For the reasons stated, the Court should disregard this finding.

1464. Mr. Qadan explained that he was principally involved in negotiating the NIPT risk-sharing agreement with Harvard Pilgrim; that negotiations spanned from April 2017 until the agreement was signed in February 2018; and that there was no guarantee the arrangement was going to be successful from the outset, given the complexities of the data involved. (Qadan (Illumina) Tr. 4143–44.)

Response to Finding No. 1464

The proposed finding is misleading to the extent it implies that Mr. Qadan was not supported by other Illumina employees during the negotiations with Harvard Pilgrim. Rather, the evidence shows that Gautam Kollu – current Chief Commercial Officer at Grail – was involved in the development of the risk-sharing agreement as part of a "cross-functional team." (Qadan (Illumina) Tr. 4254). Similarly, Rick Nida was also involved and is now working as a consultant at GenoSan Genomic and Diagnostic Commercialization Consulting. (Qadan

(Illumina) Tr. 4254). Given that two Illumina employees involved in these negotiations – Gautam Kollu and Rick Nida – now work at Grail and a consulting firm, the proposed finding should be rejected to the extent it is meant to imply that Illumina has unique knowledge as a result of the Harvard Pilgrim agreement.

1465. Mr. Qadan testified that the success of the initial NIPT risk-sharing agreement with Harvard Pilgrim enabled Illumina and Harvard Pilgrim to enter into another risk-sharing agreement in RUGD. (Qadan (Illumina) Tr. 4145.)

Response to Finding No. 1465

The proposed finding is unsupported and misleading. Mr. Qadan does not have the foundation to testify as to why Harvard Pilgrim entered into another risk-sharing agreement with Illumina. The proposed finding is also misleading to the extent it implies that Illumina's experience with risk-sharing agreements is unique. Rather, the evidence shows that Gautam Kollu – current Chief Commercial Officer at Grail – was involved in the development of the risk-sharing agreement as part of a "cross-functional team." (Qadan (Illumina) Tr. 4254). Similarly, Rick Nida was also involved and is now working as a consultant at GenoSan Genomic and Diagnostic Commercialization Consulting. (Qadan (Illumina) Tr. 4254). Similarly, Mr. Qadan admitted that Harvard Pilgrim learned from its risk-based contract with Illumina and gained experience in risk-sharing from its risk-based agreement with Illumina. (Qadan (Illumina) Tr. 4272). For the reasons stated, the Court should disregard the proposed finding as against the weight of the evidence.

1466. Mr. Qadan testified that Illumina's work with risk-sharing agreements is relevant to improving market access for Galleri, due to the reduced learning curve for any future agreements: while the NIPT agreement took 10 months to negotiate, the agreement for RUGD took roughly half the time despite the fact that Illumina had to analyze over 2,000 billing codes. (Qadan (Illumina) Tr. 4146.)

Response to Finding No. 1466

[redacted]

[redacted]

1467. *Budget Impact Modeling.* Mr. Qadan testified about Illumina's expertise in building budget impact models and their importance, explaining that: a budget impact model enables Illumina, before getting into a risk-sharing agreement, to understand what type of liability it might have and is very critical in managing the risk associated with risk-sharing agreements (Qadan (Illumina) Tr. 4127–28); in Illumina's submissions to single-payer systems outside the U.S., the economic utility component of those submissions is usually informed by its budget impact model (Qadan (Illumina) Tr. 4128); and it took one year to develop its budget impact model for NIPT and two years for RUGD. (Qadan (Illumina) Tr. 4128.)

Response to Finding No. 1467

The proposed finding is misleading to the extent it implies that Illumina's capabilities are unique. The proposed finding is also misleading to the extent it implies that Illumina's experience with risk-sharing agreements is unique. Rather, the evidence shows that Gautam Kollu – current Chief Commercial Officer at Grail – was involved in the development of the

risk-sharing agreement as part of a "cross-functional team." (Qadan (Illumina) Tr. 4254). Similarly, Rick Nida was also involved and is now working as a consultant at GenoSan Genomic and Diagnostic Commercialization Consulting. (Qadan (Illumina) Tr. 4254). Similarly, Mr. Qadan admitted that Harvard Pilgrim learned from its risk-based contract with Illumina and gained experience in risk-sharing from its risk-based agreement with Illumina. (Qadan (Illumina) Tr. 4272). For the reasons stated, the Court should disregard the proposed finding as against the weight of the evidence.

1468. Mr. Qadan explained that the broad work Illumina has done across the different applications is very important to inform its expertise of how to look at other models in the future: for example, for RUGD, in which there are over six to seven thousand genetic diseases, Illumina had to review 2,000 diagnosis codes to properly build a budget impact model (Qadan (Illumina) Tr. 4129); in CGP, the analysis Illumina has done on the impact of diagnosis on survival of cancer patients can be used in other cancer applications. (Qadan (Illumina) Tr. 4130.)

Response to Finding No. 1468

The proposed finding is misleading to the extent that it implies Illumina's capabilities are unique. The proposed finding is also misleading to the extent that it implies Illumina's experience with risk-sharing agreements is unique. Rather, the evidence shows that Gautam Kollu – current Chief Commercial Officer at Grail – was involved in the development of the risk-sharing agreement as part of a "cross-functional team." (Qadan (Illumina) Tr. 4254). Similarly, Rick Nida was also involved and is now working as a consultant at GenoSan Genomic and Diagnostic Commercialization Consulting. (Qadan (Illumina) Tr. 4254). Similarly, Mr. Qadan admitted that Harvard Pilgrim learned from its risk-based contract with Illumina and gained experience in risk-sharing from its risk-based agreement with Illumina. (Qadan (Illumina) Tr. 4272). For the reasons stated, the Court should disregard the proposed finding as against the weight of the evidence.

1469. GRAIL and Galleri. Mr. Qadan explained some of the market access challenges that GRAIL and Galleri would face. (Qadan (Illumina) Tr. 4151–55.)

Response to Finding No. 1469

The proposed finding is vague because it is unclear whether Respondents are implying Grail will face unique challenges to getting approval for Galleri. That implication is unsupported by the underlying testimony, which simply discusses Mr. Qadan's view of some of the steps of market access. (Qadan (Illumina) Tr. 4151-55). Mr. Qadan clearly would not have foundation to opine as to the comparative market access capabilities between Illumina and Grail. For the reasons stated, the Court should disregard this finding.

1470. *Medicare Adoption.* Mr. Qadan testified that: coverage by Medicare will be important in obtaining market access for Galleri, because the Medicare population, ages 65 and above, is at a higher risk of cancer; in order for Medicare to cover Galleri, Congress will likely need to pass new legislation enabling a pathway for CMS to cover multicancer screening tests; and after that pathway is created, CMS will look for FDA approval and for additional evidence of clinical utility before granting coverage. (Qadan (Illumina) Tr. 4151–53.)

Response to Finding No. 1470

[redacted]

1471. Mr. Qadan explained that his market access team has significant experience interfacing with CMS regarding Medicare coverage and that Illumina will "interact with [CMS] in a face-to-face, in different ways needed, to make sure that they understand our point of view." (Qadan (Illumina) Tr. 4153–54.)

Response to Finding No. 1471

The proposed finding is misleading to the extent it implies that Illumina has experience relevant to expanding Medicare coverage for an MCED test. As Mr. Qadan testified, "if it is a clinical application of Illumina, we interact with [CMS] in a face-to-face, in different ways needed, to make sure that they understand our point of view." MCED tests are not one of Illumina's clinical applications. (Qadan (Illumina) Tr. 4288). As such, the Court should

disregard this proposed finding to the extent it that implies Illumina has experience relating to CMS coverage relevant to MCED testing.

1472. *Private Payor Adoption.* Mr. Qadan testified that: coverage by private payors will also be important for Galleri's widespread adoption, since private payors insure most people between ages 50 and 65 who are a critical part of Galleri's target population; private payors require evidence of both clinical utility and economic utility. (Qadan (Illumina) Tr. 4154–55.)

Response to Finding No. 1472

The proposed finding is misleading to the extent that it implies Grail does not have the capabilities to generate evidence of clinical utility and economic utility on its own. [redacted]

1473. Illumina's Acceleration of Galleri's Market Access. Mr. Qadan explained that Illumina would be able to help develop clinical utility evidence for Galleri by using the partnerships Illumina has in place, by working with healthcare systems and countries outside the U.S. that Illumina has worked with before and by defining a population, especially in the U.S., that could be a good entry point with commercial payors rather than just screening everybody above the age of 50 from the outset. (Qadan (Illumina) Tr. 4155.)

Response to Finding No. 1473

[redacted]

[redacted]

1474. Mr. Qadan testified that "we have experience building real-world data, we have experience building sophisticated clinical trials, and we have relationships, whether with healthcare systems or with payors, that would enable us to do both things as well." (Qadan (Illumina) Tr. 4156.)

Response to Finding No. 1474

[redacted]

1475. Mr. Qadan also explained that Illumina could help develop economic utility evidence for Galleri using its experience from the work its done on budget impact studies and finding innovative partnerships that would enable Illumina to gather data. (Qadan (Illumina) Tr. 4156–57.)

Response to Finding No. 1475

[redacted] As such, the proposed finding should be disregarded.

1476. Mr. Qadan explained that based on his experience, Illumina is capable of contributing to the development of evidence of clinical and economic utility in a way that will accelerate the availability of Galleri on a large scale: in the U.S., Illumina will utilize the partnerships it has today to accelerate adoption by private payors; outside the U.S., in Europe, Australia and Japan, Illumina will work with single-payer systems and health technology

assessment agencies to start understanding their needs; in China, Illumina could start some of the work around patient willingness to pay for cancer screening as well as other types of studies that can inform Galleri's launch. (Qadan (Illumina) Tr. 4158–59.)

Response to Finding No. 1476

[redacted]

[redacted]

1477. Mr. Qadan testified that private payors consider the budget impact of new tests when making coverage decisions; that budget impact can delay the uptake of any new drug or test; that the budget impact of Galleri is going to be high; and that Illumina is capable of contributing to the development of evidence of economic value and cost-effectiveness of Galleri. (Qadan (Illumina) Tr. 4159–60.)

Response to Finding No. 1477

The proposed finding is misleading to the extent that it implies Grail does not have the capability to generate evidence of economic value and cost-effectiveness of Galleri. [redacted] For the reasons stated, the Court should disregard this finding.

1478. Mr. Qadan testified that based on his experience, Illumina is capable of generating evidence of the economic value and cost-effectiveness of Galleri in a way that will help to accelerate the availability of Galleri on a broad scale; that Illumina has had a plan for that acceleration in place since before this litigation commenced; that this planning work started with due diligence on Galleri when Illumina was considering buying GRAIL; and that Illumina had had discussions with partners around a pathway to accelerate Galleri's development that could reduce the budget impact of the test. (Qadan (Illumina) Tr. 4160–62.)

Response to Finding No. 1478

[redacted]

[redacted]

1479. Mr. Qadan explained that Illumina's plan for market access acceleration applied to both public and private payors; that within the U.S., Illumina would work on accelerating CMS approval through clinical utility data and accelerating regulatory approval; that outside of the U.S. work would be needed with single-payer healthcare systems, like work done with Genomics England and work done in Germany; and that work would also be done in China as a result of the favorable environment for lab-developed tests that previously did not exist. (Qadan (Illumina) Tr. 4162–63.)

Response to Finding No. 1479

[redacted]

[redacted]

1480. Mr. Qadan testified that a diagnostic aid to cancer (or DAC) could be an excellent entry point for a test like Galleri; that a DAC is a test used on patients who have started developing signs and symptoms of cancer; that Galleri performs better in patients with more advanced disease, so the test would rule out or rule in whether those patients have cancer to avoid multiple other tests; that Galleri ruling in or ruling out cancer has economic utility in that it saves money for the system in terms of further tests not being required; and that using Galleri as a DAC would initially enable Illumina to introduce Galleri into the marketplace without it having a huge impact on payors. (Qadan (Illumina) Tr. 4163–64.)

Response to Finding No. 1480

The proposed finding is irrelevant and misleading. The proposed finding is not probative to any fact at issue in the case. Moreover, it is misleading to the extent that it implies Grail does not already have a well thought out market access plan. To the contrary, the overwhelming weight of the evidence shows that Grail has a well-developed and well-resourced market access

plan. (CCFF ¶¶ 5491-5609). For the reasons stated, the Court should disregard this finding.

1481. Mr. Qadan explained that the data developed around risk factors associated with patients who tend to be positive for cancer from Galleri's use as a DAC would allow Illumina to expand its use to patients with those risk factors; that this would hopefully have an acceptable budget impact; that the third phase of this plan would be expanding the use of Galleri to the general population over the age of 50; and that the phased plan was developed with the knowledge that payors might otherwise resist a test with a high budget impact. (Qadan (Illumina) Tr. 4164–65.)

Response to Finding No. 1481

The proposed finding is irrelevant and misleading. The proposed finding is not probative to any fact at issue in the case. Moreover, it is misleading to the extent that it implies Grail does not already have a well thought out market access plan. [redacted] For the reasons stated, the Court should disregard this finding.

1482. *Illumina's Use of Consultants.* Mr. Qadan explained that in his work at Illumina and beforehand, he had used consultants: first, to build strategy and second, to build metrics to evaluate whether that strategy is working or not; and that he could not use consultants for execution, *i.e.*, to go and talk to payors on Illumina's behalf. (Qadan (Illumina) Tr. 4165.)

Response to Finding No. 1482

The proposed finding is vague because it is unclear what Mr. Qadan considers "strategy" versus "execution". The proposed finding is incorrect to the extent that it suggests Grail could not collaborate or hire entities to assist in evidence generation. [redacted] Likewise, Illumina collaborated University of Colorado researchers to design the Harvard Pilgrim study. (Qadan (Illumina) Tr. 4269-70). Similarly, Rick Nida was also involved in the development of Illumina's risk-sharing agreement and is now working as a consultant at GenoSan Genomic and

Diagnostic Commercialization Consulting. (Qadan (Illumina) Tr. 4254). [redacted]

[redacted] For the reasons stated, the Court should disregard this finding.

1483. Mr. Qadan testified that Illumina had used Real Endpoints as a consultant for its risk-sharing agreement with Harvard Pilgrim on NIPT; that Real Endpoints had conducted market research on why payors were not covering NIPT in certain pregnancies; that Real Endpoints had also managed the financial arrangement involved in the risk-sharing agreement as a third party; and that in his experience, consultants are unable to engage with payors or health systems to negotiate partnerships on behalf of their clients due to confidentiality issues associated with such negotiations. (Qadan (Illumina) Tr. 4166–67.)

Response to Finding No. 1483

[redacted]

[redacted]

1484. Mr. Qadan explained that a team of consultants could not provide the functionality for Illumina that its market access group provides; that consultants are teams that come and go, and do not have institutional expertise that is built up over time; and that, even for strategy work, it is a steep learning curve for consultants to develop the required understanding. (Qadan (Illumina) Tr. 4167–68.)

Response to Finding No. 1484

[redacted]

1485. Mr. Qadan testified that Illumina does not provide market access consulting services to other companies, as it focused its resources on its own products and could not accommodate other things; and that he was not aware of other players in the market providing consulting services for market access. (Qadan (Illumina) Tr. 4168.)

Response to Finding No. 1485

The proposed finding is vague because it is unclear who Mr. Qadan is referring to when he references "other players in the market." Mr. Qadan also does not have foundation to speak to the services that other "players" are offering. The finding is misleading to the extent that it suggests Illumina could not provide consultant services if it chooses to do so. For the reasons stated, the Court should disregard this finding.

1486. Mr. Qadan testified that market access was a high-demand, limited-supply function, particularly in genomics, and that it would be very difficult to replicate Illumina's market access functionalities because: first, there is a learning curve, especially coming to work in genomics; second, it has taken Illumina a long time to fill the roles in market access, taking two to three years before the team was in a steady state; third, Illumina's image was one of demonstrated success in this field, which could not simply be moved with an employee; and fourth, the institutional knowledge and relationships developed over time would be very hard to replicate from one company to another. (Qadan (Illumina) Tr. 4169–71.)

Response to Finding No. 1486

The proposed finding is misleading and unsupported. Mr. Qadan has never worked at a firm that does employee recruiting nor is he positioned to offer an expert opinion regarding the labor market for market access employees. (Qadan (Illumina) Tr. 4287). The proposed finding is vague because it is unclear what is meant by "demonstrated success in this field." Mr. Qadan also does not have the foundation to speak to how others view Illumina's image. [redacted] The proposed finding is incorrect that there is a steep learning curve coming to work in genomics. As Mr. Qadan testified, he had no prior experience in genomics before starting work at Illumina and it only

took him six to nine months to get up to speed. (Qadan (Illumina) Tr. 4115-16). The proposed finding is incorrect to the extent that it suggests Grail does not have a steady state market access team. [redacted] For the reasons stated, the Court should disregard this finding.

1487. Mr. Qadan testified that he was aware of GRAIL hiring two Illumina employees in the past, but neither was from the market access function; that Gautam Kollu was involved in Illumina's risk-sharing agreement with Harvard Pilgrim from the market development side of the process; that market development deals with things other than payors, including, for example, societies that are responsible for clinical guidelines; and that market access deals mainly with payor customers around the world. (Qadan (Illumina) Tr. 4171–73.)

Response to Finding No. 1487

[redacted]

1488. Mr. Qadan testified that although Illumina's market access employees are currently working on projects unrelated to Galleri, they could be redeployed to focus on expanding market access for Galleri upon Illumina and GRAIL integrating. (Qadan (Illumina) Tr. 4173–74.)

Response to Finding No. 1488

The proposed finding is misleading to the extent that it implies Illumina's market employees have excess capacity. [redacted] For the reasons stated, the

Court should disregard this finding.

1489. Mr. Qadan testified that to his knowledge, GRAIL has not achieved coverage from any payors for Galleri so far; that agreements with self-insured employers would not necessarily lead to GRAIL being covered by insurance companies; that an agreement with a health system like Providence would not necessarily lead to coverage by insurance companies; that agreements with concierge medicine providers would not necessarily lead to coverage by insurance companies; that agreements with life insurers to use Galleri would not have any impact on the willingness of private health insurers to cover the test; that risk-sharing agreements related to Galleri would not ensure that it would be able to gain market access; and that payors are not influenced in their coverage decision by how innovative a test is or by public pressure. (Qadan (Illumina) Tr. 4174–78.)

Response to Finding No. 1489

The proposed finding unsupported, misleading, and against the weight of the evidence. Mr. Qadan does not have the foundation to testify regarding Grail's capabilities or the current status of its acceptance by payers. Specifically, Mr. Qadan admitted that he did not: "GRAIL's agreements with self-insured employees [sic] could generate clinical utility data"; "GRAIL's agreements with health systems [. . .] can generate clinical utility data"; and does not know if Grail's agreements with concierge medical providers could generate clinical utility data. (Qadan (Illumina) Tr. 4273). Given the proposed finding is only supported by the unfounded, biased testimony of Mr. Qadan, the Court should disregard it on that basis alone. [redacted] For the reasons stated, the Court should disregard this proposed finding.

1490. [redacted]

[redacted]

Response to Finding No. 1490

[redacted]

1491. [redacted]

[redacted]

Response to Finding No. 1491

[redacted]

[redacted]

1492. [redacted]

Response to Finding No. 1492

[redacted]

[redacted]

1493. [redacted]

Response to Finding No. 1493

[redacted]

[redacted]

1494. [redacted]

Response to Finding No. 1494

[redacted]

1495. Mr. Qadan testified that partnerships with healthcare providers would not necessarily generate the clinical utility data required for a payor to cover a test, as physicians and payors differ in what they need. (Qadan (Illumina) Tr. 4297–98.)

Response to Finding No. 1495

[redacted]

1496. Mr. Qadan testified that Illumina's expertise with NIPT could inform Galleri; that NIPT could be an analog for Galleri in terms of payor uptake; that Illumina's understanding of budgetary impact on payor uptake could be transferred from NIPT to Galleri; and that Illumina's expertise with building risk-sharing agreements and using historical data will inform the work for Galleri. (Qadan (Illumina) Tr. 4297–4300.)

Response to Finding No. 1496

[redacted]

7. **Nicole Berry**

a. Background

1497. Nicole Berry is the Senior Vice President and General Manager of The Americas Commercial Region of Illumina. (Berry (Illumina) Tr. 833.)

Response to Finding No. 1497

Complaint Counsel has no specific response to this proposed finding.

1498. Her team's responsibilities include customer-facing actives to drive revenue and customer success with Illumina's technology. (Berry (Illumina) Tr. 833–34.) Overall, the sales organization is responsible for acquiring new customers, management of existing customers as it relates to their purchases and post-sale support. (Berry (Illumina) Tr. 834.)

Response to Finding No. 1498

Complaint Counsel has no specific response to this proposed finding.

1499. Ms. Berry possesses a bachelor's degree in biology from the University of Rochester. (Berry (Illumina) Tr. 829–30.)

Response to Finding No. 1499

Complaint Counsel has no specific response to this proposed finding.

1500. Prior to joining Illumina, Ms. Berry worked for Memorial Sloan Kettering Hospital in New York City in their cancer research lab and subsequently at Eastman Kodak Company and then Applied Biosystems. (Berry (Illumina) Tr. 828–29.) She worked in the Scientific Imaging Division at Eastman Kodak and was a district sales manager for Applied Biosystems. (Berry (Illumina) Tr. 828.)

Response to Finding No. 1500

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1501. The Transaction. Ms. Berry testified that the Transaction will not change the way that Ms. Berry's team or Illumina as a whole interacts with its customers because, in order to achieve its goal of unlocking the power of the genome, Illumina must expand access to NGS. (Berry (Illumina) Tr. 836–39.)

Response to Finding No. 1501

The proposed finding is vague and confusing. It is unclear how Illumina will "expand access to NGS" by "not chang[ing] the way… Illumina… interacts with its customers."

The proposed finding is also vague as it is unclear what "unlocking the power of the genome" means.

The proposed finding is misleading to the extent that it implies that Illumina has not changed the way it interacts with its customers after the acquisition. [redacted]

The proposed finding is misleading to the extent that it implies Illumina prioritizes "expanding access to NGS" over maximizing its profits. Illumina is a public company whose goal is maximizing revenue for its shareholders above all else. [redacted] When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value for Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). Accordingly, it does not make business sense for Illumina to sacrifice its revenues in order to achieve its goal of unlocking the power of the genome.

The proposed finding is misleading to the extent it implies that Illumina's pre-acquisition relationship with its customers was positive. The weight of the evidence shows that Illumina's

reputation among its customers was already poor pre-acquisition. [redacted] Therefore, this Court should disregard the proposed finding.

1502. Alleged Foreclosure. Ms. Berry provided testimony that debunks Complaint Counsel's theories of foreclosure, including that: Illumina has competitors who recognize the market opportunity that exists for genomics technology and this competition will only become more intensive over time (Berry (Illumina) Tr. 813); Illumina has driven down the cost of sequencing and continues to do so (Berry (Illumina) Tr. 809–12); and Illumina's products and services are only involved in certain steps of a multi-step sequencing process. (Berry (Illumina) Tr. 813–22.)

Response to Finding No. 1502

The proposed fact relies on the self-serving testimony of Illumina executive, Ms. Berry, and fails to cite to any "competitors" to support the fact that competitors "recognize the market opportunity that exists for genomics technology" and that "competition will only become more intensive over time."

The proposed finding is misleading to the extent it implies that there are any alternatives to Illumina for MCED tests. MCED customers testified they have no alternative to Illumina's

NGS platform. Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war**")).** [redacted]

[redacted]

[redacted]

The proposed finding is vague because it fails to define "certain steps." Additionally, the proposed finding is misleading to the extent it implies that customers can use non-Illumina consumables on Illumina's NGS platforms. [redacted] According to Ms. Berry, Illumina is "the only supplier of the core consumables that run on [Illumina's] instrumentation." (PX7063 (Berry (Illumina) IHT at 28)). Therefore, this Court should disregard the proposed finding.

1503. Ms. Berry testified to facts supporting the fact that Illumina's ability to withhold support from customers is limited, including: Illumina does not typically customize its sequencing instruments or core consumables for different customers (Berry (Illumina) Tr. 844); customers typically do not come to Illumina for advice on the development of their assays (Berry (Illumina) Tr. 844–45); and, outside of providing necessary documentation to regulators, Illumina does not typically provide support to customers in their efforts to get regulatory approval for their assays. (Berry (Illumina) Tr. 847–49.)

Response to Finding No. 1503

The proposed finding is vague because it fails to define or describe what "limited" or "typically" means.

The proposed finding is misleading to the extent it implies that Illumina hasn't customized its sequencing products for customers in the past. When Illumina owned more than 50% of Grail, Illumina and Grail collaborated on project development, assay development, software and data analysis, and supply chain management. (PX2541 (Illumina) at 008 (Interim Review K2-GRAIL, Feb. 2, 2017)). Illumina collaborated with Grail on "extraction methodology to improve library yields" as well as collaborated with Grail on the development of library prep and sequencing kits. Some of these kits were "built specifically for GRAIL." (PX2541 (Illumina) at 010, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)). Illumina created reagent kits "[p]urpose built for GRAIL" to accommodate Grail's high throughput ctDNA sequencing. (PX2541 (Illumina) at 008, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)). An Illumina presentation reveals that, after its spinoff, Grail had concerns that it was receiving kits from Illumina "from different lots." (PX2541 (Illumina) at 017 (Interim Review K2-GRAIL, Feb. 2, 2017)). Prior to its spinoff, Grail's [k]its were purpose built specifically for GRAIL to support single lot shipments and ease of qualification into GRAIL laboratory." (PX2541 (Illumina) at 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

[redacted] Illumina previously collaborated with Grail on "extraction methodology to improve library yields" and on the development of library prep and sequencing kits, including kits "built specifically for Grail."

(PX2541 (Illumina) at 008, 010, 017 (Interim Review: K2-Grail, Feb. 2, 2017)). Illumina's ordinary course documents charted the "[c]hanging business dynamic" between Illumina and Grail after the spinoff. The "[c]hanging business dynamic will result in Illumina functioning as a supplier compared to a product development partner," noting that Grail will shift from being a "collaborator" to a "customer." In this relationship, Illumina would limit their assistance in Grail's project development process, assay development workflow, and software and data analysis. (PX2541 (Illumina) at 008, 010 (Interim Review K-2 Grail presentation, Feb. 2, 2017 ("Illumina and Grail no longer collaborating on developing [library prep] and sequencing kits"))). After the spinoff, Illumina provided Grail "RUO kits" instead of the customized kits Grail was originally receiving. (PX2541 (Illumina) at 008, 014 (Illumina, Interim Review K-2 Grail presentation, Feb. 2, 2017)).

The proposed finding is misleading to the extent it implies that customers do not work with Illumina throughout the development product of their own tests. Furthermore, the proposed finding is misleading to the extent it implies that Illumina customers do not need Illumina's assistance to develop their tests. MCED customers need Illumina's assistance throughout the

developmental process of their test. [redacted]

[redacted].

Lastly, the proposed finding is misleading to the extent it implies that "Illumina does not typically provide support to customers in their efforts to get regulatory approval for their assays." The terms "typically," "support," and "regulatory approval" are vague because they are undefined. [redacted]. Therefore, this Court should disregard the proposed finding.

1504. Ms. Berry testified to facts supporting the fact that Illumina receives limited confidential information from customers, including that: the primary categories of confidential information that Illumina receives from its customers are their order history, some order forecasting for certain customers who choose to disclose it, certain financial information to evaluate customers' creditworthiness, and quality management records relating to troubleshooting Illumina's instruments (Berry (Illumina) Tr. 849–50); Illumina does not collect customers' sequencing data to conduct troubleshooting (Berry (Illumina) Tr. 852–53); and customers have to opt in to Illumina's troubleshooting software. (Berry (Illumina) Tr. 853.)

Response to Finding No. 1504

The proposed finding is vague because it fails to define or describe what constitutes "confidential information."

The proposed finding is vague because it fails to define or describe what "order forecasting" means. Additionally, the proposed finding is misleading to the extent it implies that Illumina cannot learn confidential information about their customers' tests from a customer's order history and order forecasting. [redacted]

[redacted]

[redacted] Ms. Berry testified that Illumina can learn customers' end uses from their purchase history. (PX7076 (Berry (Illumina) Dep. at 54-57)). Illumina is able to learn its customers' end uses from purchase history because certain Illumina consumables are better suited for certain applications. (PX7076 (Berry (Illumina) Dep. at 54-57); PX7063 (Berry (Illumina) IHT at 220-221)). Ms. Berry testified that the volume of samples a customer requires and therefore the volume of reagents purchased could increase if the customer is pursuing a clinical trial or commercializing a product. (Berry (Illumina) Tr. 664-65; PX7076 (Berry (Illumina) Dep. at 24)). [redacted]

The proposed finding is vague because it fails to define or describe what "certain financial information" and "quality management records" it is referring to.

The proposed finding is misleading to the extent it implies that Illumina does not collect customer data in order to "troubleshoot" platform problems. Illumina learns about its customers' products through embedded software in its NGS platforms. (*See* CCFF ¶¶ 2673-82).

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1505. Ms. Berry testified to facts supporting the fact that Illumina treats customer information confidentially: Illumina takes extensive measures to protect any customer information that it treats as confidential, including employee training and viewing restrictions on data stored in databases (Berry (Illumina) Tr. 853–55); and Illumina's customers cannot access the data of other customers. (Berry (Illumina) Tr. 855–56.)

Response to Finding No. 1505

The proposed finding is vague because it fails to define or describe what constitutes "confidential information."

The proposed finding is vague because it fails to define what "extensive measures" Illumina takes to "protect any customer information." Additionally, the proposed finding is

vague because it fails to explain what "employee training and "viewing restrictions" Illumina has in place.

The proposed finding is vague because the term "access" is undefined.

The proposed finding is misleading to the extent it implies that Illumina has kept customer's information confidential. [redacted]

Additionally, the proposed finding is misleading to the extent it implies that Illumina can keep customer information confidential in the future. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1506. The Open Offer. Ms. Berry testified that the Open Offer was intended as a formal documentation obligating Illumina to provide certain terms and conditions ensuring customers will not be disadvantaged relative to GRAIL, and that the cover letter specifically notes that the purpose of the Open Offer is to allay concerns relating to the Transaction. (Berry (Illumina) Tr. 856, 859.)

Response to Finding No. 1506

The proposed finding is vague because the phrase "certain terms and conditions" is undefined and unclear.

The proposed finding is unreliable because it relies solely on the self-serving testimony of an Illumina executive and the Open Offer's signatory, Ms. Berry.

The proposed finding is misleading to the extent it implies that the only reason Illumina created the Open Offer and its accompanying letters was to "ensure customers will not be disadvantaged relative to Grail." [redacted]

The proposed finding is misleading to the extent it implies that the Open Offer resolves

customer concerns regarding Illumina's incentive to disadvantage Grail's rivals post-acquisition. MCED customers have testified to their concerns regarding the Acquisition and the insufficiency of the Open Offer to prevent Illumina from favoring Grail. (*See* CCFF ¶¶ 4175-93; 4271-4465; 4484-5012). Therefore, this Court should disregard the proposed finding.

1507. Ms. Berry testified that after the announcement of the Transaction, Illumina engaged in proactive outreach to certain customers through calls and letters of intent and that the Open Offer was developed based on what Illumina learned during this outreach. (Berry (Illumina) Tr. 857, [redacted]

Response to Finding No. 1507

The proposed finding is vague because Respondents fail to define which "certain customers" Illumina reached out to regarding the proposed transaction. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1508. [redacted]

[redacted]

Response to Finding No. 1508

[redacted]

1509. [redacted]

[redacted]

Response to Finding No. 1509

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1510. [redacted]

Response to Finding No. 1510

[redacted]

[redacted]

1511. [redacted]

Response to Finding No. 1511

[redacted]

[redacted]

[redacted]

1512. *Term and Termination*. Ms. Berry testified that: the Open Offer has a twelve-year term, which was chosen to assure customers that Illumina is invested in maintaining longstanding, positive relationships with its customers (Berry (Illumina) Tr. 861–62); customers can continue to sign the Open Offer for six years after the close of the Transaction (Berry (Illumina) Tr. 861); customers can exit the Open Offer agreement at any time and for any reason (Berry (Illumina) Tr. 862–63); and Illumina cannot terminate the agreement for convenience or for a claim that a customer is infringing Illumina's IP. (Berry (Illumina) Tr. 863–64.)

Response to Finding No. 1512

The proposed finding is misleading to the extent it implies that the Open Offer can account for every situation that may occur over the next 12 years. [redacted]. Mr. Getty further testified that he is unaware of all the

issues that Guardant may face with Illumina as its supplier over the next 12 years because Guardant is "in a rapidly-evolving space that, you know, has remained stagnant very infrequently. And so ultimately just by virtue of the nature of 12 years on, it's challenging to see, but even in the sort of short term, it's difficult to even predict what's going to happen next month." (PX7105 (Getty (Guardant) Dep. 82)). Even Illumina's Ms. Berry testified that its "fair to assume" that it's difficult to know every situation that may take place over the course of a 12-year supply agreement because "there's a lot of dynamic things that are happening amongst [Illumina's] customers." (Berry (Illumina) Tr. 694; [redacted]

The proposed finding is vague because the phrase "for convenience" is undefined here and in the Open Offer. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). It is unclear and uncertain whether Illumina could terminate the Supply Agreement for a purpose that does not meet this "convenience" requirement. As [redacted]

[redacted]

The proposed finding is misleading to the extent it implies that the Open Offer states that "Illumina cannot terminate the agreement…for a claim that a customer is infringing Illumina's IP." Nowhere in the Open Offer's termination provision does it state that Illumina cannot terminate the agreement for because of IP infringement claim. (*See* PX0064 at 010 (Illumina, Open Offer Letter, Mar. 29, 2021)).

The proposed finding is misleading to the extent it implies that Illumina cares about "maintaining longstanding, positive relationships with its customers." The weight of the evidence shows that Illumina's reputation among its customers is already poor. [redacted]. Illumina's customers agree. For example, Ariosa's former CEO, Mr. Song testified that Illumina is "kind of the big bully" and

"people are scared of them." (PX7071 (Song (Omniome) IHT at 43-44)). [redacted]

Illumina's reputation among MCED developers shows that does not care much about its reputation with MCED customers because MCED customers have nowhere else to go. [redacted] Singlera's Mr. Gao testified at trial that Illumina is the "800-pound" gorilla as "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies." (Gao (Singlera) Tr. 2947-48; *see also* PX7042 (Gao (Singlera) IHT) at 88 (describing Singlera's relationship with Illumina as like being a "prisoner of war")).

Lastly, Illumina has already shown that it is willing to risk harm to its reputation to secure ownership of Grail and its future profits. Specifically, Illumina acknowledged that consummating the transaction during the pendency of the European Commission's review could lead to "other adverse consequences to, among other things, its reputation," but Illumina chose to do so anyway. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina)

Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)). Therefore, this Court should disregard the proposed finding.

1513. *Access to Services and Products*. Ms. Berry testified that: the Open Offer obligates Illumina to provide customers access to the same services to which they had access before the Transaction and to which GRAIL has access (Berry (Illumina) Tr. 865–66); Illumina can ensure adherence to this provision because Illumina's services come from a standard catalog of orderable SKUs and Illumina tracks KPIs relating to customer support functions to ensure consistent treatment (Berry (Illumina) Tr. 867–71); and Illumina would breach the Open Offer if it deliberately delayed or refused to service a customer's instrument. (Berry (Illumina) Tr. 871.)

Response to Finding No. 1513

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

[redacted]

The proposed finding is vague because it fails to define what KPIs stands for. If Respondents are referring to "Key Performance Indicators," the proposed finding is misleading

to the extent that it implies customers are able to view Illumina's internal customer support measurements or know what services another customer is receiving. Also, it is unclear how customers benefit from Illumina being able to compare how it performs in terms of service and support across individual customers or groups of customers. [redacted]. As Guardant's Mr. Getty explained, Illumina could simply say "'[w]e can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customer and therefore hurt [Guardant] competitively." (PX7105 (Getty (Guardant) Dep. at 69-71)). [redacted]

The term "ensures" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted] Moreover, the Acquisition changes Illumina's incentives to disadvantage their MCED customers. [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

The proposed finding is misleading to the extent it implies that Illumina customers will know whether Illumina breaches the Open Offer by delaying or refusing to provide service and that Illumina customers know what services are being provided to other Illumina customers. First, the Open Offer does not define "product services" or "support services." (PX0064 § 4.a. (Illumina, Open Offer Letter, Mar. 29, 2021)). Second, the Open Offer does not explain how such services could be measured to ensure consistency in treatment between Grail and its rivals. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Third, [redacted]

[redacted]

Even Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71) (testifying that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.")).

As Guardant's Mr. Getty explained, Illumina could simply say "'[w]e can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customer and therefore hurt [Guardant] competitively." (PX7105 (Getty (Guardant) Dep. at 69-71)). [redacted]

[redacted] Ultimately, "a contract is only as good as it is enforceable. And ultimately, you know, our ability – our ability, being Guardant's ability . . . to investigate adherence to the term of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)). Therefore, this Court should disregard the proposed finding.

1514. Ms. Berry testified that: the Open Offer requires that customers have access for purchase to the same sequencing instruments and core consumables to which they had access to before Transaction or to which GRAIL has access (Berry (Illumina) Tr. 865–66, 874–75); the Open Offer also requires that customers receive access to future versions of sequencing instruments and core consumables at substantially the same time as GRAIL or equivalent customers (Berry (Illumina) Tr. 876–78); and, under the Open Offer's access provisions, Illumina could not deliberately send low quality reagents, delay fulfilling a purchase order or "monkey" with supply. (Berry (Illumina) Tr. 878–79.)

Response to Finding No. 1514

The proposed finding is vague because it does not define or describe what "access" means and nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, "access" is not defined in Illumina's additional supply agreement terms which were presented in the middle of trial. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is vague because it fails to define or describe what "future versions of sequencing instruments and core consumables" means. It is unclear from this proposed finding and from Illumina's Open Offer who gets to decide whether there is a "future version" of a product. [redacted]

The proposed finding is vague because the term "substantially the same time" is

undefined. Additionally, "substantially the same time" is not used in either the Open Offer's "Access to Supplied Products" or "Access to Pre-Released Sequencing Products" provisions. (PX0064 at 006 (Illumina Open Offer agreement, Mar. 29, 2021)).

The proposed finding is misleading to the extent it implies that the Open Offer has a term that states that "customers receive access to future versions of sequencing instruments and core consumables at substantially the same time as GRAIL or equivalent customers." The Open Offer's "Access to Supplied Products" term states "Customer shall have access to the Supplied Products for purchase that GRAIL or any For-Profit Entity has access within 45 days of when GRAIL or such For-Profit Entity, as applicable, is offered such access (if not earlier) for purchase." (PX0064 at 006, shortened to 5 days in the Respondents' amended Open Offer terms published in the middle of trial). Nowhere in this term do Respondents state that customers have "access" to the "future versions" at "substantially the same time."

The proposed finding is misleading to the extent it implies that Illumina customer will know what products and consumables that Grail has "access" to. MCED customer will have no way of knowing what products Grail has access to. (*See* CCFF ¶¶ 4825-42). Additionally, the proposed finding is misleading to the extent it implies that Illumina could not make specialized products and consumables tailor made to work best with Grail's test. [redacted]

[redacted]

[redacted]

The proposed finding is vague because it fails to define or describe what the terms "monkey" and "low quality reagents" mean. The proposed finding is misleading to the extent it implies that Illumina cannot "monkey" with a customer's supply. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1515. Ms. Berry testified that the Open Offer requires Illumina, on customer request, to modify its sequencing instruments and core consumables to work more effectively with a given customer's tests (Berry (Illumina) Tr. 881); and that, even though this is not something that Illumina typically does, it was included in the Open Offer to be as customer-friendly as possible and to accommodate all possible requests Illumina might receive over the twelve-year term. (Berry (Illumina) Tr. 882.)

Response to Finding No. 1515

The proposed finding is vague because it fails to define or describe what the terms "more effectively," "typically," and "customer-friendly" mean.

The proposed finding relies solely on the self-serving testimony of Illumina's own executive and Open Offer signatory, Nicole Berry, and fails to cite to any customer testimony to support the claim that the Open Offer's development agreement provision is "customer-friendly" and "accommodate[s] all possible requests Illumina might receive over the twelve-year term."

The proposed finding is misleading to the extent it implies that the Open Offer requires Illumina, on customer request, to modify its sequencing instruments and core consumables to work more effectively with a given customer's tests." The cited testimony shows that Illumina is

not required make these modifications. Ms. Berry testified that the development agreement provisions "provides the *opportunity* for Illumina and the customer to *discuss* and develop *potentially* a separate agreement that might relate to a customer's interest in modifying a supplied product specifically for that customer and to, you know, work optimally with that customer's part of the workflow or their tests." (Berry (Illumina) Tr. 881 (emphasis added)). Thus, the Open Offer does not "require Illumina, on customer request, to modify its sequencing instruments and core consumables to work more effectively with a given customer's tests."

The proposed finding is misleading to the extent it implies that the Open Offer can "accommodate all possible requests Illumina might receive over the twelve-year terms." Nothing in the Open Offer binds Illumina to accept all requests from customers, and Illumina can decide whether or not it agrees to accommodate its customers' requests. In addition, Illumina cannot write a contract today that will address all potential issues MCED test developers may encounter during the twelve-year term. [redacted]

[redacted] Mr. Getty testified that he is unaware of all of the circumstances in which Guardant may need Illumina's assistance over the next 12 years. (PX7105 (Getty (Guardant) Dep. 82)). Mr. Getty further testified that he is unaware of all the issues that Guardant may face with Illumina as its supplier over the next 12 years because Guardant is "in a rapidly-evolving space that, you know, has remained stagnant very infrequently. And so ultimately just by virtue of the nature of 12 years on, it's challenging to see, but even in the sort of short term, it's difficult to even predict what's going to happen next month." (PX7105 (Getty (Guardant) Dep. 82)). [redacted]

Even Illumina's Ms. Berry testified that its "fair to assume" that it's difficult to know every situation that may take place over the course of a 12-year supply agreement because "there's a lot of dynamic things that are happening amongst [Illumina's] customers." (Berry (Illumina) Tr. 694).

[redacted]

[redacted] Illumina previously collaborated with Grail on "extraction methodology to improve library yields" and on the development of library prep and sequencing kits, including kits "built specifically for Grail." (PX2541 (Illumina) at 008, 010, 017 (Interim Review: K2-Grail, Feb. 2, 2017)). Illumina's ordinary course documents charted the "[c]hanging business dynamic" between Illumina and Grail after the spinoff. The "[c]hanging business dynamic will result in Illumina functioning as a supplier compared to a product development partner," noting that Grail will shift from being a "collaborator" to a "customer." In this relationship, Illumina would limit their assistance in Grail's project development process, assay development workflow, and software and data analysis. (PX2541 (Illumina) at 008, 010 (Interim Review K-2 Grail presentation, Feb. 2, 2017 ("Illumina and Grail no longer collaborating on developing [library prep] and sequencing kits"))). After the spinoff, Illumina provided Grail "RUO kits" instead of the customized kits Grail was originally receiving. (PX2541 (Illumina) at 008, 014 (Illumina, Interim Review K-2 Grail presentation, Feb. 2, 2017)). [redacted] Therefore, this Court should disregard the proposed finding.

1516. Ms. Berry testified that the Open Offer prohibits Illumina from obsolescing a sequencing instrument or core consumable as long as at least one customer continues to purchase that product (Berry (Illumina) Tr. 883.); and that this was included to ensure that customers never felt forced to transition to a new product, even if that product was better and cheaper. (Berry (Illumina) Tr. 884–85.)

Response to Finding No. 1516

The proposed finding relies solely on the self-serving testimony of Illumina's own executive and Open Offer signatory, Nicole Berry, and fails to cite to any customer testimony to

support the claim that the no-obsolescence provisions "ensures that customers never [feel] force to transition to a new product."

[redacted]

The term "prohibits" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1517. Ms. Berry testified that the Open Offer requires that, in the event of a supply shortage, Illumina must allocate any short supply in an equitable manner, rather than favoring specific customers, such as GRAIL. (Berry (Illumina) Tr. 885–86.)

Response to Finding No. 1517

The proposed finding is vague because it fails to define or describe what "supply shortage" mean and what would qualify as a "supply shortage." Nor does the Open Offer or Respondents' amended Open Offer terms, presented in the middle of trial, define what constitutes a "supply shortage." (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); *see also* RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is vague because it fails to define or describe what an "equitable manner" means.

The proposed finding relies solely upon the self-serving testimony of Illumina's Senior Vice President and General Manager of Americas, and the Open Offer signatory, Nicole Berry. Respondents do not cite to any customers that are actually subject to the Open Offer. [redacted]

The proposed finding is misleading to the extent it implies that Illumina knows how it will "allocate the existing supply in an equitable manner among its customers" if a supply shortage were to occur. Respondents' own expert Ms. Guerin-Calvert testified that she had not seen any documents or testimony that spells out how Illumina intends to allocate short supply among its customers. (RX6002 (Guerin-Calvert Trial Dep. at 154-55)). Ultimately, even with the Open Offer's supply shortages provision, [redacted]

[redacted].

The term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1518. *Pricing*. Ms. Berry testified that: the Open Offer allows customers to choose between their legacy pricing ("Grandfathered Pricing") or pricing under a universal grid ("Universal Pricing") (Berry (Illumina) Tr. 888–90); customers can choose Grandfathered Pricing for some products and Universal Pricing for others (Berry (Illumina) Tr. 892); customers who choose Universal Pricing have access to two "most-favored-nation" clauses, which ensure that they will receive pricing that is no less favorable than the pricing received by GRAIL or an equivalent customer (Berry (Illumina) Tr. 893); and if one of these most-favored-nation clauses is triggered for a customer, Illumina would be obligated to reduce the price to that customer to match the lower price received by GRAIL or an equivalent customer. (Berry (Illumina) Tr. 894.)

Response to Finding No. 1518

The proposed finding is misleading to the extent it implies that maintaining MCED customer pricing terms they had pre-acquisition means that the Open Offer restores the loss of competition that will take place post-acquisition.

The Open Offer's pricing provision fails to remedy Illumina's ability to favor Grail and offer noncompetitive prices to Grail's rivals. First, given that Grail is under Illumina's ownership, Grail's pricing is a fiction that can be easily manipulated by Illumina. As Grail's SVP of Finance, Aaron Freidin, admitted at trial that, while he does not know how Illumina will account for Grail's purchases of Illumina products, he does know "that it all eliminates and you end up with a true cost at the end when you report your financials as a public company." (Freidin (Grail) Tr. 3153). Respondents' economic expert, Dennis Carlton, likewise testified that "GRAIL doesn't technically pay a price. If you want to make up a scenario in which you force GRAIL to 'pay some price,' and you call that a transfer price . . . I'm happy to make that assumption." (RX6000 (Carlton Trial Dep. at 141-42)). Given that the Open Offer provides that a customer "will get access to the same prices" as Grail, (deSouza (Illumina) Tr. 2402), this would mean that Illumina would also have to provide its products to Grail's rivals at cost—something that Respondents have never alleged, and that Dr. Carlton admits "is not my understanding," (RX6000 (Carlton Trial Dep. at 142)). Instead, it is clear that Illumina can manufacture whatever price it wants for Grail and peg the prices for other MCED test developers to that artificial transfer price. [redacted]

[redacted]; *see* (PX7077 (Chahine (Helio) Dep. at 114-15) (Helio's Chahine testifying "Illumina would be Grail, so I don't know what giving Grail a price actually means in this context.")).

The terms "ensures" and "obligates" are misleading to the extent they imply that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1519. Ms. Berry testified that the Open Offer prevents Illumina from raising prices beyond inflation or cost of goods sold for existing products or new products that do not reflect material improvements. (Berry (Illumina) Tr. 899–901.)

Response to Finding No. 1519

The proposed finding is vague because it fails to explain or define what a "material

improvement" is. Additionally, nowhere in the Open Offer or its amended terms is "material improvement" explained. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)). It is unclear who gets to decide whether a new version of a product is considered to have a material improvement. [redacted]

The term "prevents" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

The proposed finding is misleading to the extent it implies that having no price increases replaces the competitive dynamic of a free market. Moreover, the promise of no price increases doesn't actually benefit MCED customers when the price of Illumina products will decrease substantially in the future. [redacted]

[redacted]

Illumina anticipates that sequencing costs will fall significantly over time. (PX7104 (Aravanis (Illumina) Dep. at 219-220)). Illumina's Ms. Berry testified at trial that a sequencing cost decrease from $600 to $100 is more than the 43 percent price decrease in Illumina's open offer. (Berry (Illumina) Tr. 715 (a decrease from $600 to $100 per genome would be an 83 percent decrease)). Ms. Berry testified that a $100 genome is a stated goal of Illumina's. (Berry (Illumina) Tr. 715). Therefore, this Court should disregard the proposed finding.

1520. Ms. Berry explained that the no-price-increase provision interacts with the no obsolescence provision and the Grandfathered Pricing provision to ensure that customers can continue to purchase the same products they received before the Transaction at the same prices. (Berry (Illumina) Tr. 902–03.)

Response to Finding No. 1520

The term "ensure" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted]

[redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

The proposed finding is misleading to the extent it implies that having no price increases replaces the competitive dynamic of a free market. Moreover, the promise of no price increases doesn't actually benefit MCED customers when the price of Illumina products will decrease substantially in the future. [redacted]

[redacted]

Illumina anticipates that sequencing costs will fall significantly over time. (PX7104 (Aravanis (Illumina) Dep. at 219-220)). Illumina's Ms. Berry testified at trial that a sequencing cost decrease from $600 to $100 is more than the 43 percent price decrease in Illumina's open offer. (Berry (Illumina) Tr. 715 (a decrease from $600 to $100 per genome would be a 83 percent decrease)). Ms. Berry testified that a $100 genome is a stated goal of Illumina's. (Berry (Illumina) Tr. 715). Therefore, this Court should disregard the proposed finding.

1521. Ms. Berry testified that: the Open Offer further requires Illumina to reduce the price per gigabase of sequencing using the highest throughput flow cell on the highest throughput instrument by at least 43% by 2025 (Berry (Illumina) Tr. 903–04); and by reducing the price per gigabase of sequencing, Illumina would necessarily reduce the price per sample. (Berry (Illumina) Tr. 905–06.)

Response to Finding No. 1521

The proposed finding is misleading to the extent it implies that reducing the price of sequencing by at least 43 percent is meaningful to customers. [redacted] And, internally, [redacted]

[redacted]

The proposed finding is also incomplete and misleading to the extent it implies that there will actually be a price decrease of 43 percent to MCED customers. Specifically, the proposed finding is incomplete because Respondents omit that the 43 percent discount is only off the price

per gigabase of sequencing, and it is misleading because a reduction in price per gigabase is irrelevant to MCED test developers. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)). Respondents use "price per gigabase" instead of price per read which is the most appropriate measure of price for liquid biopsy MCED tests. The ability to read one gigabase is equal to one billion nucleotides.

[redacted]

The term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive

advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1522. Ms. Berry testified that: the Open Offer allows for short-term project pricing that allows customers to access uniquely low pricing for unique situations (Berry (Illumina) Tr. 909–10); and this pricing cannot be accessed for ordinary course purchases, so if, for example, GRAIL received a discretionary discount for ordinary course purchases, that discount would trigger the most-favored-nation protections under the normal Universal Pricing grid. (Berry (Illumina) Tr. 913–14.)

Response to Finding No. 1522

The proposed finding is vague because it fails to define or describe what "uniquely low pricing" and "unique situations" means. Additionally, nowhere in the Open Offer's short term pricing term does it say the provision "allows customers to access uniquely low pricing for unique situations."

The proposed finding is vague because it fails to define what "short-term project" means. The Open Offer provides a definition for "short-term project" but that definition is also vague as it states that a short term project "means a project or circumstance giving rise to a discrete purchase of Sequencing Consumables outside of ongoing ordinary course of purchases…" (PX0064 (Illumina) at 004 (Open Offer Definition of Short Term Project, Mar. 29, 2021)). It is unclear what type of "project or circumstance" would qualify under this definition. Additionally, the proposed finding is vague because it fails to define what "similar projects" means. The Open Offer states that a customer's "Short Term Project" must be "substantially similar in size (i.e., using between 90% and 110% of the volume of Sequencing Consumables) and duration (i.e., for a period of not more than 3 months longer than the other Short Term Project)…" (PX0064 (Illumina) at 008 (Open Offer § 5h Short Term Projects, Mar. 29, 2021)).). It is unclear whether "similar projects" in this finding means "substantially similar" as defined in the Open Offer and it is also unclear who gets to decide whether a customer's project is similar.

The proposed finding is misleading to the extent it implies customers will know what short term pricing Grail receives from Illumina. MCED customers will have no way to know what pricing Grail is received from Illumina. [redacted]

Even Illumina's own executive and Open Offer signatory, Ms. Nicole Berry, testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)). Additionally, Ms. Berry testified that a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)). Therefore, this Court should disregard the proposed finding.

1523. *Regulatory Support*. Ms. Berry testified that the Open Offer obligates Illumina to provide support that is reasonably required for a customer to secure FDA approval of the customer's tests. (Berry (Illumina) Tr. 914.)

Response to Finding No. 1523

The proposed finding is vague because it fails to define or describe what "support" means. Additionally, nowhere in the Open Offer does it state that Illumina shall "provide support." (PX0064 at 008 (Illumina Open Offer agreement, dated March 30, 2021)).

The proposed finding is vague because it fails to define or describe what "reasonably

required" means. The proposed finding is misleading to the extent it implies that Illumina cannot withhold documentation or information a customer needs for FDA approval. The Open Offer states that "Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test using the Supplied Products." (PX0064 at 008 (Illumina Open Offer agreement, dated March 30, 2021)). Thus, from the language in the Open Offer, Illumina can withhold documentation or information for a customer if such information is not considered "reasonably required." It is unclear what is "reasonably required" documentation or information and who gets to make this determination.

The proposed finding is misleading to the extent it implies that the Open Offer resolves customer concerns regarding the FDA provision. [redacted]

The term "obligates" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1524. *Confidentiality*. Ms. Berry testified that the Open Offer requires Illumina to keep customers' confidential information completely separate from GRAIL and from Illumina employees who work within GRAIL. (Berry (Illumina) Tr. 916–17.)

Response to Finding No. 1524

The proposed finding is vague because it fails to define or describe what constitutes "confidential information." Additionally, nowhere in the Open Offer is the term "confidential information" define. (PX0064 (Illumina Open Offer agreement, Mar. 29, 2021)). Even Illumina executive and Open Offer signatory testified that the Open Offer does not define what constitutes

"confidential information." (Berry (Illumina) Tr. 716-18).

The proposed finding is misleading to the extent it implies customers do not have concerns regarding the Open Offer's confidentiality provision. [redacted]

Guardant's Mr. Getty testified that Illumina's firewall provision does "not at all" alleviate Guardant's concerns about the sharing of competitively sensitive information with Illumina. (PX7040 (Getty (Guardant) IHT at 188)). When asked what specifically was flawed about Illumina's firewall provision, Mr. Getty testified: "There's no enforceability of it. And with – if

it was breached, how would [Guardant] know, right." (PX7040 (Getty (Guardant) IHT at 189);

Mr. Getty testified that "individuals on [Illumina's] executive team have traded back and forth already. . . . There are individuals – you know, Illumina was an early investor in Grail, and there are individuals who are on the executive team at Illumina who hold large stakes in Grail." (PX7040 (Getty (Guardant) IHT at 188-89)). Mr. Getty of Guardant testified that it is difficult for Guardant to know whether someone from Illumina's sequencing business has spoken with someone in Grail's business. (PX7105 (Getty (Guardant) Dep. at 79-80)).

Ultimately, as Guardant's Mr. Getty testified with respect to Guardant's concerns about its confidential information being shared between Illumina and Grail, "Illumina has an incentive to share that information with GRAIL." (PX7105 (Getty (Guardant) Dep. at 100)).

[redacted]

The term "requires" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1525. *Enforcement*. Ms. Berry testified that the Open Offer provides for monitoring and enforcement mechanisms including regular audits by an external accounting firm to ensure Illumina's compliance with the Open Offer. (Berry (Illumina) Tr. 920–21.)

Response to Finding No. 1525

[redacted]

[redacted]

[redacted] Guardant's Mr. Getty testified further that "a contract is only as good as it is enforceable. And ultimately, you know, our ability – our ability, being Guardant's ability . . . to investigate adherence to the term of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)). Guardant "[doesn't] have the ability to audit. We also -- you know, in a different context, we also don't have the ability to know what goes on on a day-to-day basis at Illumina. You know, did the head of sequencing have a conversation with the head of GRAIL and say, 'Hey, look, if you go this direction or that direction, you know, by the way that's going to convey a benefit'?" (PX7105 (Getty (Guardant) Dep. at 79-80)). Mr. Getty testified that "ultimately we just have no ability to understand or actually enforce the terms of the contract, and such that, you know, they could continue to operate as they see fit, and ultimately over time, as we talked about, you know, change terms, change pricing, you know, send a technician a few months after they could have. Those things are unknowable and ultimately could be very debilitating to our business." (PX7105 (Getty (Guardant) Dep. at 79-80)). Mr. Getty explained the "nearly impossible" enforcement of a contract with Illumina: "A contract is only as good as it is enforceable. And ultimately, [Guardant's ability] to investigate adherence to the terms of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)). [redacted]

[redacted]

The term "ensures" is misleading to the extent it implies that Illumina cannot breach the terms of the Open Offer. As [redacted] Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)). Therefore, this Court should disregard the proposed finding.

1526. [redacted]

Response to Finding No. 1526

The proposed finding is vague because it fails to define or explain what "certain customers" Respondents are referring to. Additionally, the proposed finding is vague because it fails to define or explain what "unreasonable behavior" means. It is unclear who's purported

"unreasonable behavior" Respondents are referring to here.

The proposed finding relies solely on the self-serving testimony of Illumina's own executive and Open Offer signatory, Ms. Berry, and does not cite to any customer testimony to support the claim that a certain customer's behavior was "unreasonable." Therefore, this Court should disregard the proposed finding.

1527. [redacted]

Response to Finding No. 1527

[redacted]

1528. [redacted]

Response to Finding No. 1528

[redacted]

[redacted]

1528.1 [redacted]

Response to Finding No. 1528.1

[redacted]

[redacted]

1529. [redacted]

Response to Finding No. 1529

[redacted]

[redacted]

[redacted]

1530. [redacted]

Response to Finding No. 1530

[redacted]

[redacted]

[redacted]

1531. [redacted]

Response to Finding No. 1531

[redacted]

[redacted]

[redacted]

[redacted]

1532. [redacted]

Response to Finding No. 1532

[redacted]

1533. [redacted]

Response to Finding No. 1533

[redacted]

[redacted]

[redacted]

8. **John Leite (Illumina/InterVenn)**

a. Background

1534. Dr. John Leite is the Chief Business Officer at InterVenn, a company that develops a glycoproteomic platform for life scientists and the development of diagnostic tests. (Leite (Illumina/InterVenn) Tr. 2073, 2166.) As Chief Business Officer, Mr. Leite is responsible for major partnership transactions, commercial activities, corporate strategy and corporate development. (Leite (Illumina/InterVenn) Tr. 2166–67.)

Response to Finding No. 1534

The proposed finding is incomplete and mischaracterizes Dr. Leite's testimony. Dr. Leite described InterVenn as "a company that develops a glycoproteomics platform for other life scientists or for the development of our own diagnostic tests into the clinical market. (Leite (Illumina) Tr. 2073.). Therefore, this Court should disregard the proposed finding.

1535. Prior to joining InterVenn, Dr. Leite was employed at Illumina in both the Product Marketing and Development organizations. (Leite (Illumina/InterVenn) Tr. 2073, 2079–80.) In Product Marketing, Dr. Leite was responsible for the design and marketing of new diagnostic products in the Oncology Business Unit. (Leite (Illumina/InterVenn) Tr. 2073–74.) His responsibilities included Illumina's TSO-500 test, a therapy selection test. (Leite (Illumina/InterVenn) Tr. 2076.) As Vice President of Clinical Business Development, Dr. Leite was responsible for major partnership transactions with IVD providers and pharmaceutical companies. (Leite (Illumina/InterVenn) Tr. 2073.) This included the negotiation of collaboration agreements with pharmaceutical partners and IVD companies. (Leite (Illumina/InterVenn) Tr. 2080.)

Response to Finding No. 1535

The proposed finding is incomplete and mischaracterizes Dr. Leite's testimony. While employed by Illumina, Dr. Leite was "responsible for major partnership transactions with either other IVD providers or with pharmaceutical companies across the clinical space" and also "responsible for marketing in the Oncology Division," which entailed "primarily the design of new diagnostic products for … the Oncology Business Unit." (Leite (Illumina) Tr. 2073–74.) As part of those responsibilities, Dr. Leite and his group "developed a test called … the TSO-500,"

which is a "test[] for the interrogation of tumors from patients who are actively being managed for oncology or cancer care and where physicians have specific questions as to how to treat them." (Leite (Illumina) Tr. 2074.) When Dr. Leite "moved from the Oncology Division to the Business Development Group," his "responsibilities shifted from marketing of the Oncology Division products to the securing of collaborations and partnerships with industry partners, including other IVD companies and pharmaceutical companies." (Leite (Illumina) Tr. 2080.). Therefore, this Court should disregard the proposed finding.

1536. Dr. Leite has a bachelor's degree in biochemistry from Rutgers University, a Ph.D. in biochemistry and molecular genetics from the University of Pittsburgh and a post-doctoral fellowship from Caltech. (Leite (Illumina/InterVenn) Tr. 2071.)

Response to Finding No. 1536

Complaint Counsel does not dispute the proposed finding.

b. Testimony

1537. Downstream Competition. Dr. Leite testified that InterVenn specializes in a proprietary platform in glycoproteomics, a technology that does not use next generation sequencing. (Leite (Illumina/InterVenn) Tr. 2167–68.)

Response to Finding No. 1537

The proposed finding is misleading and mischaracterizes Dr. Leite's testimony. Dr. Leite testified that InterVenn is a "developer of a platform which combines laboratory workflow and proprietary software to interrogate a layer of biology called the glycoproteome," which is "a subspecialization of proteomics." (Leite (Illumina) Tr. 2167.) Dr. Leite described "glycoproteomics" as "the study of proteins and a post-translational modification is of these proteins called a glycosylation … mainly a sugar and a variety of different sugars and a variety of different structures that are attached to these proteins." (Leite (Illumina) Tr. 2167–68.) Dr. Leite never testified as to whether glycoproteomics, as a technology in general or as developed by companies besides InterVenn, uses next-generation sequencing. Rather, Dr. Leite denied that

"glycoproteomics at InterVenn use[s] next-generation sequencing" and that "InterVenn use[s] next-generation sequencing in any of its products." (Leite (Illumina) Tr. 2168). Therefore, this Court should disregard the proposed finding.

1538. Dr. Leite explained that InterVenn is developing several assays on its glycoproteomics platform including an ovarian cancer screening test, a predictive test for late-stage cancer patients who are being considered for immunotherapies and an assay for colorectal cancer screening. (Leite (Illumina/InterVenn) Tr. 2168–69.)

Response to Finding No. 1538

The proposed finding is misleading, insofar as it suggests incorrectly that InterVenn is developing an MCED test on a glycoproteomics platform. None of the tests being developed by InterVenn is an MCED test. (Leite (Illumina) Tr. 2178–80.) Dr. Leite admitted that InterVenn has not "publicly disclosed any plans to develop multicancer early detection tests." (Leite (Illumina) Tr. 2180.) Dr. Leite distinguished the glycoproteomics-based tests being developed by InterVenn from MCED tests that are based on a "next-gen sequencing platform," as InterVenn's glycoproteomics platform is "not like the next-gen sequencing platform where you're including the genes necessary for a multitest indication in the same run and analysis simultaneously." (Leite (Illumina) Tr. 2188–89). Therefore, this Court should disregard the proposed finding.

1539. Dr. Leite explained that InterVenn has several blood-based early cancer screening tests in development, the tests are based on glycoproteomics, none of them use Illumina's NGS platform and each of these tests can be run in sequence off of the same sample. (Leite (Illumina/InterVenn) Tr. 2175, 2188–89.)

Response to Finding No. 1539

The proposed finding is misleading, insofar as it suggests incorrectly that InterVenn is developing an MCED test on a glycoproteomics platform. None of the tests being developed by InterVenn is an MCED test. (Leite (Illumina) Tr. 2178–80.) Dr. Leite admitted that InterVenn has not "publicly disclosed any plans to develop multicancer early detection tests." (Leite (Illumina) Tr. 2180.) Dr. Leite distinguished the glycoproteomics-based tests being developed by

InterVenn from MCED tests that are based on a "next-gen sequencing platform," as InterVenn's glycoproteomics platform is "not like the next-gen sequencing platform where you're including the genes necessary for a multitest indication in the same run and analysis simultaneously." (Leite (Illumina) Tr. 2188–89). Therefore, this Court should disregard the proposed finding.

1540. InterVenn recently raised $201 million in Series C financing. (Leite (Illumina/InterVenn) Tr. 2177–78.)

Response to Finding No. 1540

The proposed finding mischaracterizes Dr. Leite's testimony. Respondents' counsel asked Dr. Leite, "How much did InterVenn raise in its Series C realm," to which Dr. Leite responded, "We publicly disclosed a $201 million raise." (Leite (Illumina) Tr. 2177–78). Therefore, this Court should disregard the proposed finding.

1541. Illumina's IVD Program. During Complaint Counsel's direct examination, Dr. Leite testified that an IVD test is a type of test used for diagnosis, prognosis or therapy selection that is associated with an FDA approval for a single-site or distributable application and that IVD tests are distinguished from research-use-only or laboratory-developed test ("LDT") applications. (Leite (Illumina/InterVenn) Tr. 2075–76.)

Response to Finding No. 1541

The proposed finding mischaracterizes Dr. Leite's testimony. Dr. Leite testified that "[a]n IVD test is a designation given by the regulatory agencies, whether it be CAP-CLIA or the FDA, for a type of test that is to be used for the diagnosis, prognosis, or therapy selection of patients." (Leite (Illumina) Tr. 2075.) Dr. Leite further testified that "an IVD test is traditionally associated with an FDA approval, whether that be for a site-specific application or for a distributable application, and that is to distinguish it from what's called research-use-only applications, which are not to be used in the clinical realm unless they are to be included through a validation, through a process of what's called the laboratory-developed test, and in that case, those tests are managed by CLIA." (Leite (Illumina) Tr. 2075–76). Therefore, this Court should disregard the

proposed finding.

1542. Alleged Foreclosure. Dr. Leite directly undermined Complaint Counsel's theories about Illumina's IVD strategy by testifying that Illumina never used the IVD agreements to raise the prices of kitted oncology assays, diminish innovation in kitted oncology assays or restrict competition among kitted oncology assays. (Leite (Illumina/InterVenn) Tr. 2161–62.)

Response to Finding No. 1542

The proposed finding mischaracterizes Dr. Leite's testimony and is incorrect, misleading, and against the weight of the evidence. Dr. Leite merely denied that the "purpose" of Illumina's IVD agreements was "to raise the prices of kitted oncology assays," "to diminish innovation in kitted oncology assays," or "to restrict competition among kitted oncology tests." (Leite (Illumina) Tr. 2161–62.) Dr. Leite admitted that it's "fair to say" that with respect to negotiations with customers over IVD agreements, "Illumina accepted customer proposals in those negotiations to the extent that it made financial sense for Illumina[.]" (Leite (Illumina) Tr. 2186). Dr. Leite cannot speak to the intent of others at Illumina besides himself, such as those responsible for approving Illumina's IVD agreements, and he did not purport to. (Leite (Illumina) Tr. 2161–62.) Dr. Leite also lacks personal knowledge of whether—regardless of Illumina's intent—Illumina's IVD agreements had the effect of raising prices, stifling innovation, or reducing competition in the oncology tests that Illumina's customers were developing and that would compete with Illumina's own oncology tests.

The evidence shows that Illumina's IVD agreements imposed delays, raised costs, and reduced competitiveness of its customers' oncology tests. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1543. [redacted]

Response to Finding No. 1543

[redacted]

[redacted]

[redacted]

1544. [redacted]

Response to Finding No. 1544

[redacted]

[redacted]

[redacted]

1545. [redacted]

Response to Finding No. 1545

[redacted]

[redacted]

[redacted]

1546. [redacted]

Response to Finding No. 1546

[redacted]

[redacted]

[redacted]

1547. [redacted]

Response to Finding No. 1547

[redacted]

1548. [redacted]

Response to Finding No. 1548

[redacted]

B. GRAIL

1. **Hans Bishop**

a. Background

1549. Hans Bishop has served as the Chief Executive Officer of GRAIL since 2019. (Bishop (GRAIL) Tr. 1316.) He is also a member of GRAIL's board of directors. (Bishop (GRAIL) Tr. 1316.)

Response to Finding No. 1549

The proposed finding is inaccurate and misleading to the extent it implies Mr. Bishop has served as CEO until the present. [redacted] This proposed finding also is inaccurate and misleading because it claims Mr. Bishop is a member of Grail's board of directors, but Mr. Bishop actually testified at trial that following Illumina's acquisition of Grail, Grail no longer has a board of directors. (Bishop (Grail) Tr. 1351). Therefore, the Court should disregard this proposed finding.

1550. Bishop has spent the majority of his career involved in oncology. (Bishop (GRAIL) Tr. 1361–62.) Prior to joining GRAIL, Bishop was the cofounder of June Therapeutics, which was then developing blood cancer therapies; the Chief Operating Officer of Dendreon, which was then developing a prostate cancer therapeutic; the President of Specialty Medicine at Bayer, where he oversaw an oncology portfolio; and the Global Commercial Head of Chiron, which was then developing a cancer treatment. (Bishop (GRAIL) Tr. 1361, 1365.)

Response to Finding No. 1550

The proposed finding is inaccurate and misleading. Specifically, the proposed finding claims that when Mr. Bishop was the Global Commercial Head of Chiron, the company was "*developing* a cancer treatment." However, Mr. Bishop's actual testimony at trial was: "I was global commercial head of a biotech called Chiron that also had an important treatment for cancer." (Bishop (Grail) Tr. 1361). Therefore, the proposed finding is misleading and incorrect to the extent it suggests that Chiron was researching or developing a cancer treatment while Mr. Bishop was its Global Commercial Head. Therefore, the Court should disregard this proposed finding.

1551. Bishop is the chairman of the board of Sana Biotherapeutics, which develops cancer treatments. He is also a member of the boards of Lyell Immunopharma and JW

Therapeutics, both of which develop cancer treatments, as well as of Agilent Technologies, a scientific instrument and reagent company. (Bishop (GRAIL) Tr. 1361–62.)

Response to Finding No. 1551

Complaint Counsel has no specific response to the proposed finding.

b. Testimony

1552. Background on GRAIL. Mr. Bishop testified that GRAIL is a company whose single mission is to detect cancer early when the chances of cures are greatly increased. (Bishop (GRAIL) Tr. 1362.)

Response to Finding No. 1552

Complaint Counsel has no specific response to the proposed finding.

1553. Mr. Bishop testified that: GRAIL started at Illumina; the triggering event was a curious pathologist who noticed in data from pregnant women some very unusual sequences; after discussions with Illumina's chief medical officer, the pathologist concluded that the unusual data pointed to the fact that the women had cancer; and this led to the discovery of the possibility of detecting cancer in asymptomatic patients and to the formation of GRAIL. (Bishop (GRAIL) Tr. 1362–63.)

Response to Finding No. 1553

This proposed finding is vague, unsupported, inaccurate, misleading, and contrary to the weight of the evidence. First, the proposed finding is vague as to the terms "triggering event," "data from pregnant women," and "unusual sequences." Second, Mr. Bishop lacks foundation and personal knowledge to testify regarding the origination of the idea for Grail at Illumina. Mr. Bishop joined Grail as CEO in 2019, (Bishop (GRAIL) Tr. 1316), but Illumina formed Grail in January 2016, (CCFF ¶ 29). Thus, Mr. Bishop has no personal knowledge about the formation of Grail and lacks foundation to testify about it. Indeed, Mr. Bishop testified at trial that he did not work at Illumina when it formed Grail and that the basis of his knowledge about it is just what he had "been told":

> Q. And when Illumina formed GRAIL, what did it do with the company? Did it hold the company or spin it out? What did it do?
> A. It recognized that -- I wasn't there, so I'm, you know, sharing with you what I've been

> told -- that it was an enormously risky endeavor and it would be right to form a separate company.

(Bishop (Grail) Tr. 1363).

Third, the proposed finding is incorrect, misleading, and contrary to the weight of the evidence to the extent that it seemingly implies that Illumina "discovered" MCED testing. [redacted]

[redacted] Therefore, the Court should disregard this proposed finding.

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1554. Mr. Bishop explained that, after GRAIL was formed, Illumina recognized that it was an enormously risky endeavor and it would be right to form a separate company; Illumina very generously funded the company, provided it with some of its best scientists and engineers and granted it technology rights; and, a year or two after formation, Illumina reduced its ownership in GRAIL. (Bishop (GRAIL) Tr. 1363–64.)

Response to Finding No. 1554

This proposed finding is vague, unsupported, inaccurate, misleading, and contrary to the weight of the evidence. First, vague as to the terms "enormously risky endeavor, "very generously funded," "best scientists and engineers," and "technology rights." Nowhere in the cited testimony (or in the rest of his testimony for that matter) does Mr. Bishop explain, for

example, what he meant by "enormously risky endeavor," or identify and specific risks. Similarly, nowhere in the cited testimony (or in the rest of his testimony for that matter) does Mr. Bishop specify what he meant by "generously funded" or how much specifically Illumina funded Grail. Similarly, he does not identify how many scientists or engineers were provided, nor does he identify in the cited testimony (or in the rest of his testimony for that matter) what technology was involved in the rights granted to Grail.

Second, Mr. Bishop lacks foundation and personal knowledge to testify regarding what Illumina "recognized" or what Illumina did after forming Grail. Mr. Bishop joined Grail as CEO in 2019, (Bishop (GRAIL) Tr. 1316), but Illumina formed Grail in January 2016, (CCFF ¶ 29). Thus, Mr. Bishop has no personal knowledge about the formation of Grail and lacks foundation to testify about what Illumina "recognized" or what steps Illumina took following the formation of Grail. Indeed, Mr. Bishop testified at trial that he did not work at Illumina when it formed Grail and that the basis of his knowledge about it is just what he had "been told":

> Q. And when Illumina formed GRAIL, what did it do with the company? Did it hold the company or spin it out? What did it do?
> A. It recognized that -- I wasn't there, so I'm, you know, sharing with you what I've been told -- that it was an enormously risky endeavor and it would be right to form a separate company.

(Bishop (Grail) Tr. 1363). Moreover, Mr. Bishop was never designated as a corporate designee on any topics (neither for Grail or Illumina) and thus it is improper for him to testify as to what Illumina "recognized."

Third, the proposed finding is incorrect, misleading, and contrary to the weight of the evidence to the extent that it implies that Illumina spun off Grail because it was "an enormously risky endeavor." [redacted]

[redacted]

[redacted] Therefore, the Court should disregard this proposed finding.

1555. Mr. Bishop testified that: he joined the GRAIL Board in 2018 and became CEO in 2019; he joined because he believed that, if successful, GRAIL could make an enormous contribution and that it had the opportunity to reduce suffering and deaths from cancer in a cost-effective manner; and, since he joined GRAIL, GRAIL has validated the performance of Galleri in a trial approved by the FDA, built all of the infrastructure necessary to reliably deliver that test and made the Galleri test available to patients for the first time. (Bishop (GRAIL) Tr. 1364, 1366–67.)

Response to Finding No. 1555

The proposed finding is vague, misleading, and contrary to the weight of the evidence in part. Specifically, the proposed finding is vague as to the term "validated the performance of Galleri in a trial approved by the FDA" as it is unclear what is meant by the terms "validated," what aspects of Galleri's "performance" were "validated," and what "trial" is referred to in this finding. [redacted] Therefore, the Court should disregard this part of Respondents' proposed finding.

The proposed finding is also misleading and contrary to the weight of the evidence to the extent it is used to suggest that Grail has "validated" that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of today, Galleri has been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct.");

see generally [redacted] Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). [redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010

(E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. [redacted]

Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

Complaint Counsel agrees with Respondents' proposed finding that Grail has built all of the infrastructure necessary to reliably deliver that test and made the Galleri test available to patients for the first time.

1556. Mr. Bishop testified that GRAIL is now at a delicate and risky inflection point; GRAIL is now a commercial company and that comes with many new challenges, including the need to build different types of teams, to serve customers and to continue to develop technologies. (Bishop (GRAIL) Tr. 1367.)

Response to Finding No. 1556

The proposed finding is vague, incorrect, contrary to the weight of the evidence, and inconsistent with Respondents' other proposed findings of fact. First, this proposed finding is inconsistent with Respondents' immediately preceding proposed finding, where Respondents claim that Grail has "built all of the infrastructure necessary to reliably deliver that test and made the Galleri test available to patients for the first time." Second, the proposed finding is vague as to the terms "delicate and risky inflection point," and "new challenges" as none of the risks or challenges are identified in either the proposed finding or the underlying cited testimony. Finally, the proposed finding is misleading and contrary to the weight of the evidence to the extent it implies that Grail requires the assistance of Illumina to successfully continue the development and commercialization of Galleri. [redacted]

Additionally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1557. The Galleri Test. Mr. Bishop testified that: Galleri is a blood test that is intended to detect a cancer signal and enable the earlier diagnosis and treatment of cancer; the test looks at abnormalities in methylation regions in DNA that come from a tumor and is able to identify that as distinct and separate from healthy tissue; the test detects more than 50 types of cancer with a

very low false positive rate and offers the doctor insight into the tissue of origin of the cancer; and GRAIL is optimistic it will be able to detect more cancers in the future. (Bishop (GRAIL) Tr. 1373, 1375.)

Response to Finding No. 1557

The proposed finding is vague, incomplete, and misleading. First, the proposed finding is misleading and incorrect to the extent it suggests that Grail can detect more than 50 types of cancer in an asymptomatic population as there is no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Nor is there clinical evidence that Galleri can provide early detection of 20 cancers in an asymptomatic population, or ten, or even eight. As of today, Galleri has been clinically shown to detect only seven types of early stage cancer in an asymptomatic screening population – a fact conceded by Respondents' own expert. ((Cote Tr. 4000-4001) ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct."); *see generally* CCFF ¶¶ 6206-6394 (Appendix B: Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

Respondents seek to conflate the detection of cancer signals among previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant issue of an MCED test's capability to identify early-stage cancers in an asymptomatic screening population. Galleri is being developed (1) as a multi-cancer early detection test (2) for use in screening an asymptomatic population. (*See, e.g.*, RPFF ¶ 342 (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms")). The fact that Galleri can detect signals for certain cancers once those cancers reach Stage IV does not support Galleri's ability to detect those cancers early. (*See, e.g.*, CCFF ¶ 6223). Respondents' own expert conceded that Stage IV cancer "is almost always incurable and will eventually result in the death of the patient."

(RX3869 (Cote Rebuttal Report) ¶ 31). Likewise, the fact that Galleri can detect signals for certain cancers among individuals who have already been diagnosed with cancer does not support Galleri's ability to detect those cancers in an asymptomatic screening population.

Grail has released results from two clinical studies of Galleri: the CCGA study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993). [redacted]. Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). The only other study of Galleri for which interim results have been released, PATHFINDER, likewise fails to support the notion that Galleri can provide early detection of 50+ cancers in an asymptomatic population. Grail's Chief Medical Officer, Dr. Ofman, acknowledged the challenges associated with generating the clinical evidence necessary to actually support a 50-cancer early screening claim when he admitted: "To find all 50 cancer

types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that." (RPFF ¶ 398.4 (quoting Ofman (Grail) Tr. 3298). Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

The proposed finding is also vague, misleading, and incorrect with respect to the phrase "very low false positive rate." It is unclear what is meant by "low false positive," and this claim is misleading and incorrect to the extent it implies a specific sensitivity for Galleri. Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (*i.e.* in an asymptomatic screening population). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Grail admits as much itself.

[redacted]

[redacted]

The proposed finding is incomplete and misleading to the extent it suggests that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population.

[redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Among other factors, some of the blood samples

in CCGA were "collected from participants with cancer after biopsies had been carried out," which the authors note "could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." Galleri's reported tissue of origin accuracy was worse for Stage I-II cancers than for Stage III-IV cancers in CCGA (*See* RX3430 at 6, Figure 4 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2]). This fact suggests that Galleri's CSO performance will be worse in an asymptomatic screening population that does not include previously diagnosed Stage III and Stage IV cancer patients, as the CCGA study did.

[redacted] Additionally, Galleri's CSO prediction feature does not obviate the need for additional diagnostic evaluation, including diagnostic imaging such as PET-CT. (*See* PX0063 at 002 (Grail, https://grail.com/galleri, accessed Apr. 29, 2021) ("A test result of 'Cancer Signal Detected' requires confirmatory diagnostic evaluation by medically established procedures (*e.g.* imaging) to confirm cancer").

The proposed finding is misleading to the extent it suggests that [redacted] Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive

Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

Grail undertook the PATHFINDER study to assess the extent and types of diagnostic testing that will be required to achieve diagnostic resolution following a positive Galleri result and cancer signal of origin ("CSO") predication. [redacted] If Grail had already established the extent to which PET-CT and other types of diagnostic testing would be required to achieve diagnostic resolution when Galleri is used in a real-world setting, such a study would not be necessary. Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical

Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

For all of these reasons, the proposed finding should be disregarded.

1558. Of the 50 cancers that Galleri can detect, only five—prostate, cervix, breast, colon and lung—have screening tests available. (Bishop (GRAIL) Tr. 1374.)

Response to Finding No. 1558

Complaint Counsel has no specific response to the proposed finding.

1559. Mr. Bishop testified that GRAIL currently only has one lab, but that it is building a second lab to invest in additional test capacity, invest in new cost-reducing technology and create new capacity for clinical trials. (Bishop (GRAIL) Tr. 1377–78.)

Response to Finding No. 1559

This proposed finding is misleading and incorrect to the extent the phrase "is building" implies that Grail has not completed building its second lab which provides robust testing capacity for Galleri. Record evidence shows that as part of its laboratory operations planning,

[redacted]

[redacted] Therefore, this proposed finding should be disregarded in part.

1560. Mr. Bishop testified that, while GRAIL uses the Illumina NovaSeq, the choice to use it relates mainly to the fact that it was used when Illumina founded GRAIL; GRAIL uses a variety of reagents and consumables and not all of these inputs are from Illumina; and Illumina has no role in running the Galleri test. (Bishop (GRAIL) Tr. 1381–82.)

Response to Finding No. 1560

The proposed finding is vague, incomplete, misleading, and contrary to the weight of the evidence. First, the claim that Grail uses the Illumina Novaseq "mainly" because "it was used when Illumina founded GRAIL" is incomplete and misleading. As the trial record demonstrates, Illumina's NovaSeq is the only NGS platform that meets MCED test developers' requirements and allows MCED tests to achieve their goal of saving patient lives. [redacted]

[redacted] According to Grail's CFO, [redacted]

Second, the assertion that "Illumina has no role in running the test" is misleading and contradicted by the weight of the evidence. [redacted] As Exact's CEO, Kevin Conroy, testified at trial, [redacted].

Finally, the assertion that Grail uses a "variety or reagents and consumables" is incomplete and misleading because the critical reagents and consumables for Galleri are from Illumina. Illumina admits that [redacted] Therefore, this proposed finding should be disregarded.

1561. Mr. Bishop described the Galleri test process from a patient perspective: a doctor makes the decision as to whether or not it is appropriate to prescribe Galleri; a blood sample is collected; that blood sample is sent to GRAIL's laboratory in Northern California where all Galleri tests are processed; and then, once testing is complete, test results are returned to the doctor, who communicates them to the patient. (Bishop (GRAIL) Tr. 1375–76.)

Response to Finding No. 1561

Complaint Counsel has no specific response to the proposed finding.

1562. Mr. Bishop also described the Galleri test process at the laboratory: first, the DNA is chemically isolated from the patient's blood; next, the sample undergoes bisulfite conversion to essentially preserve the methylation or the epigenetic signature associated with that DNA sample; then, in library preparation, plates are loaded with different samples from different patients; followed by a series of steps to enrich the signal that comes from each sample; then, the sequencing step, measuring the methylation; after that, duplexing and alignment to separate out the results before the methylation call is run; next, the computer algorithm makes a determination as to whether a cancer signal is detected or not; and, finally, a series of quality control steps to ensure that no samples have been contaminated. (Bishop (GRAIL) Tr. 1379–80.)

Response to Finding No. 1562

The proposed finding is incomplete and misleading to the extent it implies that Illumina's NGS sequencing is not used as part of the Galleri test process at Grail's laboratory. [redacted] (PX0043 at

011 (Grail 2020 Form S-1); PX7069 (Bishop (Grail) IHT at 208-10)). [redacted] Therefore, the proposed finding should be disregarded.

1563. The report provided to physicians contains information about whether a cancer signal has been detected; a prediction about the cancer signal of origin; and detail regarding the test's technical performance, including sensitivity, specificity and PPV. (Bishop (GRAIL) Tr. 1382.)

Response to Finding No. 1563

The proposed finding is incomplete and misleading to the extent it suggests that Grail can [redacted] Therefore, the proposed finding should be disregarded.

1564. Mr. Bishop testified that Galleri's sensitivity is a little less than 70% when the results from 12 prespecified important cancers are averaged and just under 45% when results from all 50 cancers are averaged; these numbers should not be compared to similar numbers for a single cancer tests because it is an apples-to-pears comparison. (Bishop (GRAIL) Tr. 1383–84.)

Response to Finding No. 1564

The proposed finding is incomplete, misleading, and contradicted by the weight of the evidence because it implies that Grail knows what the sensitivity of its MCED test will be in Galleri's intended use population (*i.e.* in an asymptomatic screening population). Grail cannot say today what the sensitivity of its MCED test will be in Galleri's intended use population (*i.e.*

in an asymptomatic screening population). The authors of the CCGA-3 sub-study – which Respondents rely upon for their 50-cancer claims – make this point explicitly in their article, cautioning that "CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). The authors of the CCGA-2 sub-study provide the same caveat about CCGA, stating: "to understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA. (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020)). Grail admits as much itself.

[redacted]

The proposed finding is incomplete and misleading to the extent it suggests that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population.

The proposed finding is also misleading and contradicted by the weight of the evidence to the extent it implies that Grail [redacted]. Therefore, the proposed finding should be disregarded.

1565. Mr. Bishop testified that: a low false positive rate for a test like Galleri is very important, because a false positive can create enormous stress and having a positive test can come with medical risk and economic costs; and the PPV for Galleri is over 40% which is significantly higher than the PPV for mammograms and other single-cancer screening tests. (Bishop (GRAIL) Tr. 1385–86.)

Response to Finding No. 1565

The proposed finding is incomplete and misleading. [redacted] Therefore, the proposed finding should be disregarded.

1566. Mr. Bishop testified that detecting tumor of origin is important because it points the doctor to the right follow up, makes the test easier to use, speeds up time to diagnosis and can reduce unnecessary work-ups and whole-body imaging; the Galleri test correctly identifies tumor signal of origin approximately nine times out of ten; and Galleri detects tumor signal of origin though the blood and without a body scan. (Bishop (GRAIL) Tr. 1387–88.)

Response to Finding No. 1566

The proposed finding is incomplete and misleading to the extent that it suggests that there is agreement or consensus that algorithmic tissue of origin prediction will ultimately prove superior to other methods of identifying the location of cancer as part of MCED testing, such as PET-CT. [redacted]

[redacted]

The proposed finding is incomplete and misleading to the extent it suggests that Galleri's cancer signal of origin ("CSO") performance has been clinically established in Galleri's intended

use population. Reliable clinical data does not yet exist about how Grail's cancer signal of origin feature would perform in an asymptomatic screening population. [redacted] Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95). The authors of the Grail's CCGA-2 and CCGA-3 sub-studies themselves acknowledge that CCGA is not reflective of performance in a screening population. RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2] ("[T]o understand [Galleri's] performance in an asymptomatic screening population will require additional studies" beyond CCGA.")); (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021) [CCGA-3] ("CCGA is a case-control study, and as such, is not reflective of performance in a screening population.")). Among other factors, some of the blood samples in CCGA were "collected from participants with cancer after biopsies had been carried out," which the authors note "could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." Galleri's reported tissue of origin accuracy was worse for Stage I-II cancers than for Stage III-IV cancers in CCGA (*See* RX3430 at 6, Figure 4 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020) [CCGA-2]). This fact suggests that Galleri's CSO performance will be worse in an asymptomatic screening population that does not include previously diagnosed Stage III and Stage IV cancer patients, as the CCGA study did.

The CSO accuracy numbers reported in CCGA do not indicate the likelihood that a particular CSO prediction accurately identifies the location of an individual's' cancer because (1) CCGA did not involve an asymptomatic screening population, (2) the study excluded false positives when assessing CSO accuracy, and (3) Grail counts Galleri's CSO predictions as "correct" *even in instances when Galleri does not actually identify the location of the underlying cancer.* (*See* Complaint Counsel Reply Brief at 50-54). Additionally, Galleri's CSO prediction feature does not obviate the need for additional diagnostic evaluation, including diagnostic imaging such as PET-CT. (*See* PX0063 at 002 (Grail, https://grail.com/galleri, accessed Apr. 29, 2021) ("A test result of 'Cancer Signal Detected' requires confirmatory diagnostic evaluation by medically established procedures (*e.g.* imaging) to confirm cancer").

The proposed finding is misleading to the extent it suggests that Galleri's [redacted]. Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

[redacted] Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). Therefore, the proposed finding should be disregarded.

1567. Mr. Bishop testified that GRAIL is focused on three customer groups for Galleri: large, self-insured employers, integrated health systems and limited direct-to-physician channels called concierge practices; these are groups among which the test can be adopted even though it is not covered by a patient's insurance. (Bishop (GRAIL) Tr. 1401–03.) To expand beyond these groups, GRAIL would need to be successful with a PMA, achieve broad-based reimbursement, reduce test cost and increase production capacity. (Bishop (GRAIL) Tr. 1403.)

Response to Finding No. 1567

The proposed finding is incomplete and misleading to the extent it implies that Grail could not achieve a PMA, achieve broad-based reimbursement, reduce test cost, or increase production capacity as quickly on its own as it could via the Acquisition. [redacted]. Therefore, the proposed finding should be disregarded.

1568. Mr. Bishop testified that Galleri is currently priced at $949; Galleri's long-term goal is for this price to be reduced; and becoming part of Illumina will accomplish this goal by allowing Galleri to scale faster, invest in automation and robotics, reduce reliance on sequencing and reduce other costs. (Bishop (GRAIL) Tr. 1404–05.)

Response to Finding No. 1568

The proposed finding is vague, misleading, incomplete, and contradicted by the weight of the evidence. The proposed finding is vague because it does not specify (either in the finding or in the underlying cited testimony), the amount by which the price would allegedly be reduced, how much faster Galleri might be "scaled," what "reduced reliance on sequencing" means, and what types of costs "other costs" refers to.

The proposed finding is incomplete and misleading because it omits that Grail's long-term goal for Galleri was to substantially reduce the price of Galleri apart from the Acquisition. For example, according to the August 20, 2020 Morgan Stanley presentation to the Grail board

of directors, Grail projected reducing the average sales price (ASP) of Galleri to as low as [redacted]

The proposed finding is misleading and contradicted by the weight of the evidence to the extent that the phrase "by becoming part of Illumina" implies that such initiatives are merger-specific efficiencies. For example, Respondents failed to demonstrate that the supply chain and operational efficiencies are merger specific. [redacted]). Further, the record evidence shows that these efficiencies are not merger specific because they could be achieved by Grail on its own. For example, at the time of the Acquisition, Grail was already engaged in two major initiatives designed to dramatically reduce the COGS of Galleri: [redacted]

Similarly, as part of its laboratory operations planning, [redacted] (CCFF

[redacted]

As a result of these initiatives, Grail projected [redacted] Therefore, this proposed finding should be disregarded.

1569. Galleri's Alleged Competitors. Mr. Bishop testified that he has become familiar with other early detection liquid biopsy tests in development as a part of his job through expert colleagues, reading the literature, reading press reports and reading reports on data presented at medical meetings. (Bishop (GRAIL) Tr. 1388.)

Response to Finding No. 1569

The proposed finding is incomplete and misleading to the extent it implies that Mr. Bishop did not become familiar with other early detection liquid biopsy test through other means besides "colleagues, reading the literature, reading press reports and reading reports on data presented at medical meetings." For example, during the development of its MCED test, Grail formed a competitive intelligence team, known as its "CIA team" [redacted]

[redacted]

1570. Mr. Bishop testified that, while he is aware of other companies developing single cancer tests, Galleri will complement, not compete with, single-cancer tests: single-cancer tests are optimized for detecting a single cancer, whereas Galleri's goal is to maximize the number of cancers we detect early; and single-cancer tests are used with individuals with an underlying risk, while Galleri is designed to be used with the general population. (Bishop (GRAIL) Tr. 1389–93.)

Response to Finding No. 1570

The proposed finding is vague, misleading, and contradicted by the weight of the evidence. The proposed finding is vague because it does not specify which companies are the "other companies" developing single cancer tests. To the extent "other companies" is referring to referring to [redacted], the proposed finding is misleading, incorrect, and contradicted by the weight of the evidence which shows that all of those companies are developing MCED tests. [redacted] Therefore, the proposed finding should be disregarded.

1571. Mr. Bishop explained that the more cancers a test can detect, the greater the clinical benefit for society and the patient; a test that detects a small number of cancers would be less helpful unless a patient was at an elevated risk for those cancers. (Bishop (GRAIL) Tr. 1400–01.)

Response to Finding No. 1571

The proposed finding is vague, incomplete, and misleading. The proposed finding is vague because it is unclear whether Mr. Bishop was testifying about specific tests or just opining on tests generally. The proposed finding also is vague because it is unclear what "clinical benefit" Mr. Bishop is referring to, or how it would be measured.

The proposed finding is misleading to the extent that it implies Grail's Galleri test will provide greater clinical benefits than other MCED tests. To the extent the phrase "test that detects a small number of cancers" is referring to [redacted], the proposed finding is misleading, incorrect, and contradicted by the weight of the evidence which [redacted]

Finally, Mr. Bishop lacks foundation for his opinion in this proposed finding. In his trial testimony, Mr. Bishop prefaced the cited testimony with the caveat "I believe" rather than testifying he knew and that basis for his knowledge. (Bishop (Grail) Tr. 1400). Therefore, the proposed finding should be disregarded.

1572. *Guardant*. Mr. Bishop testified that Guardant is focused on a blood-based, single-cancer test to detect colon cancer; he has not read any publications indicating that Guardant's test will detect more than one cancer; and this test will not compete against Galleri. (Bishop (GRAIL) Tr. 1389–93.)

Response to Finding No. 1572

The proposed finding is vague, misleading, incomplete, and contrary to the weight of the evidence. First, the proposed finding misstates Mr. Bishops testimony. Mr. Bishop did not

testify that he had not read any publications indicating that Guardant's test would not detect more than one cancer; instead, he testified that his answer was referring to a *single-cancer* test being developed by Guardant. Specifically, Mr. Bishop testified:

> Q. Have you read any publications that indicate that the test Guardant is developing will detect any cancers other than colorectal?
> A. The test I'm referring to is a single-cancer focused test.

(Bishop (Grail) Tr. 1390).

Similar, the proposed finding is extremely misleading to the extent it suggests that Guardant's MCED test will not compete with Galleri. Respondents cite Mr. Bishop's testimony that he did not believe "Guardant's test" to compete against Galleri. But the proposed finding is misleading because Mr. Bishop made clear he was talking about Guardant's single-cancer test, not its MCED. *See (*Bishop (Grail) Tr. 1390-91 (testifying that he was only referring to Guardant's "single cancer focused test" and "the reason that we should not use Galleri instead of any of those single tests is because those single tests are optimized for detecting those single cancers")).

[redacted]

[redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1573. *Freenome*. Mr. Bishop testified that Freenome is developing a blood-based test for colorectal cancer; that he has not read anything that would suggest this test can detect any other cancers or that Freenome has another test that will identify other cancers; and that Galleri does not expect to compete with Freenome's test. (Bishop (GRAIL) Tr. 1393–94.)

Response to Finding No. 1573

The proposed finding is vague, misleading, incomplete, and contrary to the weight of the evidence because it implies that Freenome is [redacted]

[redacted]

[redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1574. *Exact/Thrive*. Mr. Bishop testified that: there is no publicly available data on the latest iteration of Exact's test; the last reported results report approximately eight or ten cancers; Exact has been unable to replicate results from earlier trials; if Exact's technology is viable, the lack of published data on Exact's test is extraordinary; at least one of Exact's reported technologies would involve two sequential tests and a PET-CT scan; there is no data suggesting

that Exact can identify cancer signal of origin; and it is currently not possible to understand whether Exact will compete with Galleri. (Bishop (GRAIL) Tr. 1394–97.)

Response to Finding No. 1574

The proposed finding is vague, unsupported, misleading, and contrary to the weight of the evidence. First, the proposed finding is vague because it is unclear what "test" is referred to in this finding, including whether it is referring to Exact's single-cancer test or MCED CancerSEEK. Similarly, it is vague what is referred to by "last reported results," "earlier trials," and "one of Exact's reported technologies."

Second, to the extent the proposed finding refers to Exact/Thrive's MCED test, the proposed finding is unsupported because Mr. Bishop lacked foundation to testify about the current features and capabilities of Exact/Thrive's *current* MCED test, CancerSEEK. Specifically, in response to a question about whether Mr. Bishop expected "Exact's test in development to compete with Galleri if it ever becomes available for purchase," testifying that "[t]hat's really not possible to understand at this point in time because we don't know what the performance features of such a test may be." (Bishop (Grail) Tr. 1397). Indeed, even in this proposed finding itself, Respondents concede that "there is no publicly available data on the latest iteration of Exact's test."

Third, the proposed finding is contradicted bt the weight of the evidence which shows that [redacted]

[redacted]

[redacted]

[redacted]

Additionally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Finally, this Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. Therefore, the proposed finding should be disregarded.

1575. *Singlera*. Mr. Bishop testified Singlera has published clinical trials conducted in China regarding a multicancer test; that GRAIL's technical scientists follow the data carefully and are concerned that the data has confounding factors which suggest that the technology is still in early stages; and it is not possible to know, based on current data, whether Singlera's test would compete with Galleri. (Bishop (GRAIL) Tr. 1397–99.)

Response to Finding No. 1575

The proposed finding is vague, unsupported, misleading, and contrary to the weight of the evidence. First, the proposed finding is vague with respect to the terms "data," "confounding factors," and "early stages." For example, it is unclear in either the proposed finding or the underlying cited testimony what specific data Mr. Bishop was referring to, whether the data refers to Singlera's *current* version of its MCED test, or what (and if so, how) the alleged factors may impact Singlera's *current* version of its MCED test.

Second, the proposed finding is unsupported because Mr. Bishop lacked foundation to testify about Singlera's current version of its MCED test. Specifically, when asked a question about competition with Singlera's PanSeer MCED test, Mr. Bishop admitted that, "[a]gain, I – I don't know . . . I don't think it's possible to know." (Bishop (Grail) Tr. 1399).

Further, the proposed finding is misleading and against the weight of the evidence to the extent Respondents imply Singlera is not actively developing its PanSeer MCED test. Singlera has already completed a proof-of-concept study of its PanSeer test in China on 100,000 people, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30); *see also* Gao (Singlera) Tr. 2878-79). Singlera's PanSeer MCED test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study, with the goal of offering a "pan-cancer" test. (Gao (Singlera) Tr. 2881). Singlera has already invested between $60-100 million on the development of the PanSeer MCED test and expects to launch it as an FDA approved test by 2028. (Gao (Singlera) Tr. 2888-89; PX7042 (Gao (Singlera) IHT at 96)).

[redacted]

[redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1576. Mr. Bishop testified that, today, GRAIL is not competing against any of the above companies. (Bishop (GRAIL) Tr. 1401.)

Response to Finding No. 1576

The proposed finding should be disregarded as misleading, unsupported, unreliable, and against the weight of the evidence. Respondents have cited the self-serving testimony of Grail's former CEO, Hans Bishop, whose testimony does not even support Respondents' proposed finding. With respect to Guardant and Freenome, Mr. Bishop was testifying about competition between the companies' *single-cancer* screening tests and Grail's Galleri MCED test. (*See* Bishop (Grail) Tr. 1390-91 (testifying that he was only referring to Guardant's "single cancer focused test" and "the reason that we should not use Galleri instead of any of those single tests is because those single tests are optimized for detecting those single cancers"); 1393-94 (testifying that he does not think Freenome's single-cancer colorectal test will compete with Grail's Galleri "[f]or the same reasons we've covered, that [single-cancer tests] should be used in combination"). Complaint Counsel does not disagree that Grail's Galleri does not compete with single-cancer screening tests. (*See* CCFF ¶¶ 634-87).

With respect to Thrive/Exact and Singlera, Mr. Bishop testified that he *did not know* if their MCED tests would compete with Grail's Galleri. (Bishop (Grail) Tr. 1397 (in response to a

question about whether he expected "Exact's test in development to compete with Galleri if it ever becomes available for purchase," testifying that "[t]hat's really not possible to understand at this point in time because we don't know what the performance features of such a test may be"); 1399 (replying to a question about competition with Singlera's PanSeer MCED test that "[a]gain, I – I don't know . . . I don't think it's possible to know"). This proposed finding should thus be completely disregarded as misleading, unsupported, and unreliable.

Even if supported, this proposed finding is entirely against the evidence including even contradictory testimony from Mr. Bishop. Mr. Bishop also testified that patients benefit from having multiple MCED tests in development, explaining: "difficult problems are, by definition, hard to solve, and having a multitude of different approaches is a good thing." (PX7069 (Bishop (Grail) IHT at 154-56)). He went on to emphasize that "one of the exciting things about the horizon scanning we do and the field in general is the number of different approaches different companies are taking." (PX7069 (Bishop (Grail) IHT at 154-56). Whereas Grail has chosen to focus on cfDNA methylation, he explained that other companies have chosen to focus on protein analysis and others on multi-omics that "combin[e] those different modalities." (PX7069 (Bishop (Grail) IHT at 154-56)). These approaches, Bishop emphasized, all intend to reach the same goal—"to get to the highest-performing technology." (PX7069 (Bishop (Grail) IHT at 154-56)). [redacted]

[redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. The proposed finding should thus be wholly disregarded as unsupported, unreliable, and against the weight of the evidence.

1577. Risks Faced By GRAIL. GRAIL met with Illumina to discuss a potential acquisition in the summer of 2020. (Bishop (GRAIL) Tr. 1407.) In 2020, GRAIL was also considering an IPO to fulfill ongoing needs for substantial amounts of capital to run operations. (Bishop (GRAIL) Tr. 1407.) While one other company had expressed interest in purchasing GRAIL, they never made an offer. (Bishop (GRAIL) Tr. 1407.)

Response to Finding No. 1577

The proposed finding is incomplete and misleading to the extent it implies an IPO (or other alternatives to the Acquisition) was not a viable option for Grail to raise funding, and contradicted by the weight of the evidence. Prior to the Acquisition, [redacted]

[redacted]

[redacted] Therefore, the proposed finding should be disregarded.

1578. Mr. Bishop testified that, in deciding between an IPO and a transaction with Illumina, he had many meetings with investors and shareholders; there was substantial concern about an IPO because the pathway to reimbursement was unpredictable and long, investors did not understand the scientific reports, investors were concerned that performance could deteriorate as results become more advanced and investors struggled to value GRAIL, given the lack of similar precedents. (Bishop (GRAIL) Tr. 1407–11.)

Response to Finding No. 1578

The proposed finding is incomplete and misleading to the extent it implies an IPO (or other alternatives to the Acquisition) was not a viable option for Grail to raise funding, and contradicted by the weight of the evidence. Prior to the Acquisition, [redacted]

[redacted] Therefore, the proposed finding should be disregarded.

1579. Mr. Bishop testified that GRAIL's S-1 discloses many risks faced by GRAIL. (Bishop (GRAIL) Tr. 1411–22.)

Response to Finding No. 1579

Complaint Counsel agrees that GRAIL's S-1 discloses risks faced by GRAIL, including competition that Grail expects to face from other MCED developers, *see* (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)), and that Grail relies "on Illumina, Inc. as a sole supplier for our next-generation sequencers and associated reagents. . . ." (CCFF ¶ 1067). The proposed finding is misleading, however, to the extent it implies [redacted]

1580. The Transaction. Mr. Bishop testified that there were multiple discussions by the GRAIL board regarding the Transaction; the GRAIL board had deep experience in contemplating the different paths ahead and had done so multiple times with different companies; and the GRAIL board employed the advice of expert advisors. (Bishop (GRAIL) Tr. 1422.)

Response to Finding No. 1580

The proposed finding is vague, incomplete, and misleading. The proposed finding is vague because it states that board has "deep experience" but does not specify what type of

experience the board possessed, or whether (and if so, how) experience was relevant to analysis of the Acquisition. The proposed finding also is vague as to the phrase "multiple times with different companies" as it is unclear how many times, and which companies, the board had alleged experience with. Similarly, the phrase "different paths" is vague because it is not clear what paths the board considered for Grail according to this finding. Finally, "expert advisors" is vague because it is unclear how many, and what type, of alleged expert advisors were retained.

The proposed finding is incomplete and misleading to the extent it implies that that Grail board did not seriously consider an IPO at the same time as it considered the Acquisition. Record evidence demonstrates that as [redacted] Through a series of [redacted]

Finally, the proposed finding is misleading to the extent it implies that the only way Grail can achieve its alleged efficiencies, [redacted]

[redacted] Therefore, the proposed finding should be disregarded.

1581. Mr. Bishop testified that the GRAIL Board unanimously decided to be acquired by Illumina because it had determined that it would result in the best outcome for patients and reduce the risks of the challenges ahead of GRAIL. (Bishop (GRAIL) Tr. 1423, [redacted]

Response to Finding No. 1581

The proposed finding is unsupported speculation, is vague, misleading, irrelevant, and contradicted by the weight of the evidence. First, Complaint Counsel objects to this proposed finding because Mr. Bishop lacks foundation to testify as to whether the Acquisition will result in any acceleration efficiencies (*i.e.*, broader of faster adoption) or international efficiencies. Mr. Bishop admitted at trial that "integration planning hasn't started" between Illumina and Grail. (Bishop (Grail) Tr. 1425). Indeed, record evidence shows that Respondents have yet to [redacted]

For example, with respect to the FDA acceleration claims, Febbo conceded that [redacted] Mr. Bishop likewise testified at trial that [redacted]

Dr. Ofman, Grail's Chief Medical Officer, similarly explained at trial that [redacted]

[redacted] Therefore, Mr. Bishop lacks foundation to testify regarding any alleged efficiencies, and the proposed finding should be dismissed as unsupported speculation.

Second, the proposed finding is vague as to the terms "best outcomes," "risks", and "challenges." To the extent, the proposed finding is referring to Respondents' acceleration efficiencies, the proposed finding is misleading and contradicted by the weight of the evidence. *See* Complaint Counsel's Post-Trial Reply Brief § V.B.

Third, to the extent the proposed finding implies that Grail did not have options apart from a merger with Illumina to secure additional financing, the proposed finding is misleading and contradicted by the weight of the evidence. For example, prior to the Acquisition, [redacted]

[redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1582. [redacted]

Response to Finding No. 1582

[redacted]

[redacted]

[redacted]

[redacted]

1583. Mr. Bishop testified that he expects that GRAIL will be able to achieve its mission of detecting cancer early faster as part of Illumina. (Bishop (GRAIL) Tr. 1423.)

Response to Finding No. 1583

The proposed finding is unsupported speculation, is vague, misleading, and contradicted by the weight of the evidence. First, Complaint Counsel objects to this proposed finding because

Mr. Bishop lacks foundation to testify as to whether the Acquisition will result in any acceleration efficiencies. Mr. Bishop admitted at trial that "integration planning hasn't started" between Illumina and Grail. (Bishop (Grail) Tr. 1425). Indeed, record evidence shows that Respondents have yet to [redacted] For example, with respect to the FDA acceleration claims, Febbo conceded that [redacted] Dr. Ofman, Grail's Chief Medical Officer, similarly explained at trial that [redacted]

Therefore, Mr. Bishop lacks foundation to testify regarding any alleged efficiencies, and the

proposed finding should be dismissed as unsupported speculation.

Second, the proposed finding is vague as to the term "faster" as neither the proposed finding nor the underlying testimony specifies how much faster the Acquisition could allegedly accelerate Galleri. In fact, Mr. Bishop conceded that he could not quantify how much sooner he expects Grail to receive PMA approval if Grail receives assistance from Illumina versus without. (Bishop (Grail) Tr. 1426).

[redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1584. Efficiencies. Mr. Bishop testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives (Bishop (GRAIL) Tr. 1370–71); accelerating

market access to Galleri (Bishop (GRAIL) Tr. 1368–72, 1403); research and development efficiencies (Bishop (GRAIL) Tr. 1367); supply chain and operational efficiencies (Bishop (GRAIL) Tr. 1372, 1404–05); and accelerating international availability of Galleri. (Bishop (GRAIL) Tr. 1406.)

Response to Finding No. 1584

The proposed finding is unsupported speculation, is vague, misleading, and contradicted by the weight of the evidence. First, Complaint Counsel objects to this proposed finding because Mr. Bishop lacks foundation to testify as to whether the Acquisition will result in any efficiencies. Mr. Bishop admitted at trial that "integration planning hasn't started" between Illumina and Grail. (Bishop (Grail) Tr. 1425). Indeed, record evidence shows that Respondents have yet to [redacted] Dr. Ofman, Grail's Chief Medical Officer, similarly explained at trial that [redacted]

[redacted] Similarly, with respect to payer acceleration, Dr. Febbo admitted at trial that [redacted] Therefore, Mr. Bishop lacks foundation to testify regarding any alleged efficiencies, and the proposed finding should be dismissed as unsupported speculation.

The proposed finding is vague because:

- it refers to "saving lives" but does not explain how (or how many) lives will be saved;
- it refers to "accelerating market access to Galleri" but does not explain how (or how much more quickly) market access will be accelerated;
- it refers to "research and development efficiencies" but does not specify what these efficiencies are or how they would be achieved;
- it refers to "supply chain and operational efficiencies" but does not specify what aspects of Grail's supply chain or operations these efficiencies allegedly impact; and
- it refers to "accelerating international availability of Galleri" but does not specify, how, where, or when this would be achieved.

The proposed finding is also misleading and contradicted by the weight of the evidence to the extent it implies any of these alleged efficiencies are verifiable, merger-specific, cognizable efficiencies. *See* Response to RPFF ¶¶ 1585-1595.

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1585. *Saving Lives.* Mr. Bishop testified that many cancers are diagnosed when it is very difficult or impossible to cure them; offering a test to all patients, regardless of financial means, will enable detection of cancer at an earlier stage, improving patients' probability of survival and reducing the cost of cancer treatment for those patients. (Bishop (GRAIL) Tr. 1370–71.)

Response to Finding No. 1585

Complaint Counsel does not dispute that MCED tests "are poised to turn the tide in the war on cancer" by "detect[ing] multiple cancers at early stages, leading to improved outcomes and saving lives." Complaint Counsel's Post-Trial Brief at 1. However, Respondents have not demonstrated the Acquisition will actually accelerate the adoption of Galleri, and therefore, Respondents have failed to show their Acquisition would save any lives. *See* Complaint Counsel's Post-Trial Reply Brief § V.A-B. Therefore, to the extent the proposed finding implies that the Acquisition is likely to result in any lives saved, the proposed finding should be disregarded.

1586. Mr. Bishop testified that combining with Illumina will increase GRAIL's likelihood of success and enable it to accomplish its goals faster. (Bishop (GRAIL) Tr. 1371–72.)

Response to Finding No. 1586

The proposed finding is vague, incomplete, misleading, and contradicted by the weight of the evidence. The proposed finding is vague because it is unclear what is meant by "increase GRAIL's likelihood of success" as this could theoretically refer to numerous aspects of Grail's business. For example, it is unclear which (if any) of the multiple products Grail is developing is being referred to in this finding. Similar, the phrase "enable it to accomplish its goals faster" is vague because it is unclear what "goals" are being referred to in the proposed finding, and whether the goals relate to any relevant product.

To the extent "goals" refers to goals associated with the research, development, and commercialization of Galleri, and "faster' refers to Respondents' acceleration claims regarding

Galleri, the proposed finding is unsupported, misleading, and contradicted by the weight of the evidence. The proposed finding is unsupported because Mr. Bishop lacks foundation to testify regarding whether an Acquisition by Illumina would result in any cognizable efficiencies related to FDA approval or payer acceleration. *See* Response to RPFF ¶ 1584.

Further, the proposed finding is misleading and contradicted by the weight of the evidence because record evidence clearly shows that Respondents' FDA and payer acceleration claims are not cognizable. *See* Complaint Counsel's Post-Trial Reply Brief § V.B.

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. Therefore, the proposed finding should be disregarded.

1587. *Acceleration of Market Access.* Mr. Bishop testified that GRAIL intends to seek a PMA approval from the FDA; that seeking a PMA approval is a long and complicated process; and that PMA approval is a prerequisite to getting payor and insurance coverage for Galleri. (Bishop (GRAIL) Tr. 1368, 1370, 1403.)

Response to Finding No. 1587

The proposed finding is vague, incomplete, and misleading to the extent it implies that Grail was not on track to obtain PMA approval on its own (*i.e.*, apart from the Acquisition). The phrase "long and complicated process" is vague as it is unclear what part (or parts) of the FDA's PMA approval process it refers to, how "long" the process is, and how it is allegedly complicated.

Second, the proposed finding is incomplete and misleading to the extent it implies that Grail was not already working on PMA approval for Galleri and was not on track to obtain FDA

approval on its own. Record evidence shows that Grail is [redacted] Thus, evidence indicates that independently Grail is on track—in fact ahead of schedule—to receive FDA approval and payer reimbursement for Galleri. Therefore, the proposed finding should be disregarded.

1588. Mr. Bishop testified that Illumina is a globally respected and experienced company when it comes to dealing with regulatory authorities (Bishop (GRAIL) Tr. 1372); the Transaction will increase GRAIL's chances of success with the PMA (Bishop (GRAIL) Tr. 1372); [redacted]

Response to Finding No. 1588

[redacted]

[redacted]

[redacted]

[redacted]

1589. Mr. Bishop testified that the path to reimbursement for preventative services, including screening tests, was unclear, but that obtaining widespread reimbursement was very important. (Bishop (GRAIL) Tr. 1417.)

Response to Finding No. 1589

The proposed finding is vague as it is unclear whether "screening tests" refers to MCED tests and whether "widespread reimbursement" refers to coverage by payers for MCED testing.

[redacted]

1590. Mr. Bishop expects that Illumina's deep expertise interacting with regulators de-risks and maybe speeds up the speed at which regulatory approvals, which are a prerequisite for reimbursement, are achieved (Bishop (GRAIL) Tr. 1417–18, 1421–22); that Illumina will be able to help GRAIL reduce its costs, which will make Galleri more attractive to payors and healthcare organizations (Bishop (GRAIL) Tr. 1417–18); and that [redacted]

Response to Finding No. 1590

The proposed finding is unsupported speculation, is vague, misleading, and contradicted by the weight of the evidence. First, Complaint Counsel objects to this proposed finding because Mr. Bishop lacks foundation to testify as to whether the Acquisition will result in any efficiencies, including any alleged acceleration. Mr. Bishop admitted at trial that "integration planning hasn't started" between Illumina and Grail. (Bishop (Grail) Tr. 1425). [redacted]

[redacted] For example, with respect to the FDA acceleration claims, Febbo conceded that {[redacted] Dr. Ofman, Grail's Chief Medical Officer, similarly explained at trial that [redacted]

Therefore, Mr. Bishop lacks foundation to testify regarding any alleged efficiencies, and the proposed finding should be dismissed as unsupported speculation. *See also* Response to RPFF ¶ 1586.

The proposed finding is vague because:

- it refers to "regulators" but does not specify which regulators;
- it refers to "speeds up the speeds" but does not specify how much more quickly or how;

- it refers to "costs" but does not identify which costs; and
- it refers to "more attractive" but does not explain in what specific ways Galleri would allegedly be more attractive.

The proposed finding is incomplete and contradicted by the weight of the evidence to the extent it suggests that Illumina could assist Grail with accelerating its PMA for Galleri. Contrary to Mr. Bishop's vague and unsupported assertions that Illumina has experience that could assist with FDA approval of Galleri's PMA, the evidence demonstrates that Illumina lacks the necessary expertise and capabilities. For example, [redacted] Moreover, although Illumina claims it can help accelerate Galleri's FDA approval, record evidence reveals that Illumina, itself, has had little success navigating the FDA process. [redacted] Illumina also lacks experience conducting the types of large-scale clinical trials that Grail, as a standalone company, has already begun to obtain FDA approval. [redacted] Illumina's lack of relevant

FDA experience and ongoing struggles with the FDA process, there is little evidence to show how Illumina can accelerate Grail's test.

Additionally, the propose finding is incomplete, misleading, and contrary to the weight of the evidence to the extent it suggests that Grail is not (or is unable) to pursue FDA acceleration independently. [redacted] Grail's regulatory team, in its own words, possesses [redacted]

[redacted] (CCFF ¶ 5349).

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1591. *Research and Development Efficiencies.* Mr. Bishop explained that GRAIL has, as a very high priority, reducing the cost of its test and is investing heavily in robotics and other improvements (Bishop (GRAIL) Tr. 1368–69); Illumina has the experience and ability to make GRAIL's technology faster and cheaper to run (Bishop (GRAIL) Tr. 1372); Illumina understands the importance of ongoing investment in R&D (Bishop (GRAIL) Tr. 1416); after the Transaction GRAIL will no longer be at the whims of the market and will be part of a successful, profitable company that understands what it takes to invest and develop innovative science (Bishop (GRAIL) Tr. 1419); Illumina will give GRAIL the predictability needed to engage in ongoing investments in people and technology (Bishop (GRAIL) Tr. 1372–73); the resources needed for R&D will be greatly secured (Bishop (GRAIL) Tr. 1416); and Illumina has the technical capabilities to contribute to GRAIL's performance. (Bishop (GRAIL) Tr. 1415–16.)

Response to Finding No. 1591

The proposed finding is unsupported speculation, misleading, and contradicted by the weight of the evidence. [redacted]

[redacted]

The proposed finding is incomplete and contradicted by the weight of the evidence to the extent it suggests that Illumina could assist Grail with achieving any R&D efficiencies. The weight of the evidence shows that the claimed R&D efficiencies that Respondent contends will result from the merger are "novel" *discoveries* and other scientific breakthroughs, which by definition, cannot be identified with specification. Respondents do not—because they cannot—identify the specific breakthroughs, products, or benefits which may result, nor do Respondents identify the timing, likelihood, or cost to achieve such alleged benefits. [redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1592. *Supply Chain and Operational Efficiencies.* Mr. Bishop testified that Illumina's experience and success in opening labs and producing complicated equipment will help GRAIL scale up (Bishop (GRAIL) Tr. 1372, 1404–05); and that [redacted]

Response to Finding No. 1592

The proposed finding is unsupported speculation, misleading, and contradicted by the weight of the evidence. [redacted]

[redacted] Similarly, as part of its lab operations planning, [redacted] For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1593. *Expanding International Availability*. Mr. Bishop testified that GRAIL will need to obtain regulatory approvals outside of the United States and that Illumina's commercial experience and relationships around the world will help GRAIL reach those customers faster. (Bishop (GRAIL) Tr. 1368, 1372, 1406–07.)

Response to Finding No. 1593

The proposed finding is vague, unsupported, incomplete, contradicted by the weight of the evidence, and irrelevant. The proposed finding is vague because it refers to "regulatory approvals outside of the United States" but neither the proposed finding nor the underlying

testimony identifies any specific countries where such alleged expansion would occur. Similarly, the proposed finding refers to achieving such approvals "faster" but fails to specify in either the proposed finding or underlying testimony how much faster such approvals would occur.

[redacted]

The proposed finding is incomplete and contradicted by the weight of the evidence to the extent it suggests that Illumina could assist Grail with obtaining regulatory approvals outside the United States faster than Grail could on its own. For example, Respondents produced no evidence regarding in which specific countries the international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion would only be achieved through a merger with Illumina. [redacted]

Further, the proposed finding is irrelevant to the extent it implies that international expansion is a cognizable efficiency. As this court has held, "[a]n anticompetitive merger cannot

be justified on the basis of asserted efficiencies outside the relevant market." *Otto Bock*, 2019 WL 2118886, at *49 (Chappell, A.L.J.); *see also Phila. Nat'l Bank,* 374 U.S. at 370; *Univ. Health*, 938 F.2d at 1222; *St. Alphonsus*, 778 F.3d at 790; *Heinz*, 246 F.3d at 715. Here, the relevant geographic market is the United States. *See* Complaint Counsel's Post-Trial Brief at 63-66; (CCFF ¶¶ 831-885). Thus, to the extent the proposed finding is used to support a claim that there will be international expansion related efficiencies, the proposed finding is irrelevant as that alleged benefit, which would occur outside the United States, cannot offset competitive harm within the United States. *See Otto Bock*, 2019 WL 2118886, at *53 (Chappell, A.L.J.) ("Furthermore, the evidence is insufficient to justify a conclusion that the asserted efficiencies would benefit consumers in the United States, which is the relevant geographic market. Accordingly, Respondents' rebuttal argument based on efficiencies is rejected.").

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1594. As Mr. Bishop explained, "Before the Illumina transaction, [international expansion] was something that we had extraordinary limited plans on because we didn't have the team or financial resources to contemplate that outside of one market . . . Illumina has established operations and the relevant teams of experts and laboratories in certain instances in many countries around the world." (Bishop (GRAIL) Tr. 14056.)

Response to Finding No. 1594

The proposed finding is vague, incomplete, misleading, irrelevant, and contradicted by the weight of the evidence. The terms "limited plans" is vague. The proposed finding is incomplete and contradicted by the weight of the evidence, which shows that Grail already had

robust international expansion plans and operations in place at the time of the Acquisition. For example, record evidence shows that [redacted] **).**

Further, the proposed finding is irrelevant to the extent it implies that international expansion is a cognizable efficiency. As this court has held, "[a]n anticompetitive merger cannot be justified on the basis of asserted efficiencies outside the relevant market." *Otto Bock*, 2019 WL 2118886, at *49 (Chappell, A.L.J.); *see also Phila. Nat'l Bank,* 374 U.S. at 370; *Univ. Health*, 938 F.2d at 1222; *St. Alphonsus*, 778 F.3d at 790; *Heinz*, 246 F.3d at 715. [redacted] Thus, to the extent the proposed finding is used to support a claim that there will be international expansion related efficiencies, the proposed finding is irrelevant as that alleged benefit, which would occur outside the United States, cannot offset competitive harm within the United States. *See Otto Bock*, 2019 WL 2118886, at *53 (Chappell, A.L.J.)

("Furthermore, the evidence is insufficient to justify a conclusion that the asserted efficiencies would benefit consumers in the United States, which is the relevant geographic market. Accordingly, Respondents' rebuttal argument based on efficiencies is rejected.").

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. Therefore, the proposed finding should be disregarded.

1595. Mr. Bishop also testified that Illumina's sales, marketing and distribution infrastructure, which has been very successful at commercializing new technology, will enable GRAIL to commercialize Galleri at a faster scale. (Bishop (GRAIL) Tr. 1420–21, [redacted]

Response to Finding No. 1595

The proposed finding is unsupported speculation, misleading, and contradicted by the weight of the evidence. [redacted]

Second, the proposed finding is misleading, incomplete, and contradicted by the weight of the evidence (including Mr. Bishop's own testimony) to the extent it implies the Acquisition is likely to result in any cognizable commercialization efficiencies. [redacted]

Finally, this proposed finding is inherently speculative. For support, Respondents cite only to the unfounded, self-serving testimony of Mr. Bishop (who received over $100 million in compensation when Illumina acquired Grail, (Bishop (Grail) Tr. 1355)), that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

2. **Josh Ofman**

a. Background

1596. Joshua Ofman is the Chief Medical Officer and Head of External Affairs at GRAIL. (Ofman (GRAIL) Tr. 3276.)

Response to Finding No. 1596

Complaint Counsel does not disagree with the proposed finding.

1597. Dr. Ofman joined GRAIL in July 2019. (Ofman (GRAIL) Tr. 3276.) As Chief Medical Officer and Head of External Affairs, Dr. Ofman oversees external affairs (including corporate communications and government affairs); clinical development; medical affairs; and the regulatory, quality and clinical compliance aspects of GRAIL. (Ofman (GRAIL) Tr. 3281.)

Response to Finding No. 1597

Complaint Counsel does not disagree with the proposed finding.

1598. Prior to joining GRAIL, Dr. Ofman worked at Amgen for about sixteen years in a variety of roles in clinical development, medical affairs and government affairs; for the last eight years of his time at Amgen, Dr. Ofman served as Worldwide Head of Market Access, Global Planning, Global Health Policy and Outcomes Research. (Ofman (GRAIL) Tr. 3276–77.)

Response to Finding No. 1598

Complaint Counsel has no specific response to the proposed finding.

1599. Dr. Ofman has authored over one hundred publications, focusing primarily on call technology assessment, which refers to the evaluation of human, clinical and economic harms and benefits associated with the introduction of innovative technology. (Ofman (GRAIL) Tr. 3278.)

Response to Finding No. 1599

The proposed finding is vague because the terms "publications," "primarily," "economic harms and benefits," and "innovative technology" are undefined. It is unclear whether the term "publications" refers to peer-reviewed publications or includes non-peer reviewed publications, working papers, web/blog postings, or other written materials. No context is given for the term "economic harms and benefits"; Complaint Counsel notes that Dr. Ofman is not an economist, there is no evidence that he has received economic training. Therefore, this Court should disregard the proposed finding.

1600. Dr. Ofman has a bachelor's degree from UC Berkeley and a medical decree from UC Irvine. He worked as an intern and resident in internal medicine and a fellow in digestive diseases at UCLA. He participated in the Robert Wood Johnson scholars program at the RAND/UCLA program and he received a master's of science in health services from the UCLA School of Public Health. (Ofman (GRAIL) Tr. 3277–78.)

Response to Finding No. 1600

Complaint Counsel has no specific response to the proposed finding.

b. Testimony

1601. The Galleri Test. Dr. Ofman testified that Galleri is GRAIL's first validated test. (Ofman (GRAIL) Tr. 3284.)

Response to Finding No. 1601

Complaint Counsel does not dispute that Dr. Ofman testified as indicated in the proposed finding. The meaning and significance of Dr. Ofman's testimony, however, is vague and the proposed finding is thus incomplete. The proposed finding is vague because the term "validated test" is undefined and it is unclear what Dr. Ofman means by that term. Dr. Ofman testified on that Galleri has been both analytically and clinically validated. (Ofman (Grail) Tr. 3284-3285). Later, however, Dr. Ofman testified that one of the "most important criterion [sic] by which to evaluate a multicancer test" is that "there should be robust analytical and clinical validation *at population scale to support the test's deployment in the population*." (Ofman (Grail) Tr. 3288-

3291 (emphasis added) (cited in RPFF ¶ 1610). Galleri has not completed clinical studies at population scale. [redacted]

[redacted]:

[redacted]

[redacted] Goswami (Illumina) Tr. 3186 (stating that the test developer "takes all responsibility for certifying the test and validating it"); PX7097 (Felton (Thermo Fisher) Dep. at 51) (stating that an LDT test itself is "self-validated" under CLIA/CAP regulation in the U.S.)) It is unclear from Dr. Ofman's testimony what *specifically* Galleri's "validation" involved and whether any entity other than Grail has "validated" Galleri's performance. Therefore, this Court should disregard the proposed finding.

1602. Dr. Ofman testified regarding the process of the Galleri test: it starts with a simple blood draw from the participant; then plasma (in which circulating DNA resides) is

isolated from the blood, amplified, and subjected to bisulfite sequencing, which reveals the patterns of methylation status of the DNA; Galleri looks at over a million of these methylation sites in over a hundred thousand regions of the genome and uses a machine learning algorithm to discriminate what is a cancer signal from what is a noncancer signal; and then, if a cancer signal gets detected, Galleri examines and weights different features from these patterns to predict the tissue of origin or where in the body the cancer signal arose. (Ofman (GRAIL) Tr. 3285–88.)

Response to Finding No. 1602

The proposed finding is vague because the term "regions of the genome" is ambiguous and undefined; it is unclear whether this refers to genes, amplicons, or another designation. Therefore, this Court should disregard the proposed finding.

1603. Dr. Ofman testified that GRAIL has validated the Galleri test through the largest case-control study that's been done for early detection, called the Circulating Cell-free Genome Atlas (CCGA) study; GRAIL is conducting two very large cohort noninterventional studies, STRIVE and SUMMIT, in women getting mammograms and men and women getting low-dose CT for high-risk lung cancer screening; GRAIL is conducting an interventional study, PATHFINDER, in 6,600 men and women screening eligible with no suspicion of cancer; GRAIL is also conducting the largest, real-world, pragmatic, randomized clinical trial ever done in the field of genomics, in the U.K. in 140,000 screening-eligible individuals. (Ofman (GRAIL) Tr. 3291–300.)

Response to Finding No. 1603

Complaint Counsel does not disagree that Grail has conducted CCGA, a case-control study; is conducting PATHFINDER, a roughly 6,600 participant interventional study; and is conducting STRIVE and SUMMIT, two large noninterventional cohort studies. [redacted]

Certain portions of the proposed finding are vague. The proposed finding is vague because the term "for early detection" is ambiguous and it is unclear if Dr. Ofman is referring to tests related to multicancer early detection specifically, early detection of cancer more generally, or any sort of early detection across cancer and other health conditions. The proposed finding is

also vague because the meaning of the term "validated" is undefined and unclear. (*See* Response to RPFF ¶ 1602 above).

1604. [redacted]

Response to Finding No. 1604

[redacted]

1605. [redacted]

Response to Finding No. 1605

[redacted]

1606. [redacted]

Response to Finding No. 1606

[redacted]

1607. Dr. Ofman testified that GRAIL has locked version 2 of Galleri, which is the version currently available on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (Ofman (GRAIL) Tr. 3301–03.)

Response to Finding No. 1607

Complaint Counsel does not disagree with the proposed finding, but notes for completeness that Dr. Ofman testified that Grail hopes to use an updated version of Galleri for its PMA submission. (*See* Ofman (Grail) Tr. 3301)).

1608. Dr. Ofman testified that, although GRAIL's Galleri test runs on NGS sequencers supplied by Illumina, Illumina has had no involvement in GRAIL's development of Galleri at all since Illumina spun out GRAIL; Illumina has had no involvement in any of GRAIL's clinical trials or studies; GRAIL has not been required to share information about Galleri's specifications or its algorithm with Illumina; and GRAIL developed its Galleri test without Illumina. (Ofman (GRAIL) Tr. 3306–07.)

Response to Finding No. 1608

Complaint Counsel has no response to the proposed finding.

1609. Dr. Ofman testified that Galleri received breakthrough device designation from the FDA in 2018 as well as investigational device exemption (IDE). (Ofman (GRAIL) Tr. 3305–06.)

Response to Finding No. 1609

The proposed finding is vague because it could be read to suggest (incorrectly) that Grail obtained FDA approval for its IDE application in 2018, rather than 2020. Complaint Counsel does not otherwise disagree with the proposed finding.

1610. Other Alleged MCED Tests. Dr. Ofman testified that GRAIL developed the following criteria to evaluate whether a multicancer early detection test will be well-received by regulatory agencies and clinical entities: it needs to find the majority of deadly cancers; it has to have a very low false positive rate and a much higher positive predictive value (PPV) than what is typically seen with single-cancer screening tests; it has to be able to predict the tissue of origin; it needs to be simple and easy to use; and there should be robust analytical and clinical validation at population scale to support the test's deployment in the population. (Ofman (GRAIL) Tr. 3288–91.)

Response to Finding No. 1610

The proposed finding is vague, misleading, and unreliable. The proposed finding is misleading because Dr. Ofman did not use the term "other alleged MCED tests." In addition, Dr. Ofman's testimony relates to a demonstrative exhibit created by Respondents, which Dr. Ofman

described as "a slide that we've been developing to try to capture what we believe are the most important criterion [sic] by which to evaluate a multicancer early detection test." (Ofman (Grail) Tr. 3288). The proposed finding is unreliable because Respondents cite only to the self-serving testimony of a Grail executive related to document created specifically for this litigation, uncorroborated by any ordinary course documents or analysis.

The proposed finding is also vague because the terms "well-received," "clinical entities," "deadly cancers," "very low," "much higher," and "typically seen," are ambiguous and undefined. Therefore, this Court should disregard the proposed finding.

1611. Dr. Ofman testified that Galleri is not competing with any of the single-cancer liquid biopsy tests in development by companies like Exact Sciences, Guardant Health and Freenome or with liquid biopsy tests that detect two or three cancers; the real value of Galleri is in detecting cancers for which people are not currently being screened. (Ofman (GRAIL) Tr. 3310–13.)

Response to Finding No. 1611

The proposed finding is vague, confusing, misleading, and against the weight of the evidence. The proposed finding is vague because the term "real value" is vague and undefined.

The proposed finding is confusing because it strings together multiple purported facts out of context without providing specific citations for each. This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged multiple proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Respondents' combination of multiple statements is confusing and misleading to the extent Respondents intend to state one fact.

The composite nature of the proposed finding is misleading. Dr. Ofman made his statement about the "real value of Galleri" in response to a question asking him specifically

whether a physician would "compare Galleri against one of these single-cancer liquid biopsy tests that's looking for colon cancer." (*See* Ofman (Grail) Tr. 3311-3312)). Respondents place the quote from Dr. Ofman in a way that suggests it relates to tests "that detect two or three cancers," which is misleading. When asked whether he "expect[ed]" that Galleri would compete against a liquid biopsy test that detected two or three cancers, Dr. Ofman testified that he is "not aware of a test out there like that right now," but that he did not expect that Galleri would compete against a hypothetical test for "stomach an esophageal cancer" only. (Ofman (Grail) Tr. 3310–13.))

The proposed finding is also misleading, and against the weight of the evidence, to the extent it suggests suggest that Grail is not competing against Exact, Guardant, and Freenome. Dr. Ofman merely testified that Galleri is not competing with those companies' single-cancer tests because single-cancer screening is "very different than doing a multicancer early detection test" because "you're looking for one cancer." (Ofman (Grail) Tr. 3311). [redacted] However, this Court should disregard the remainder of this proposed finding for the reasons stated above.

1612. Efficiencies. Dr. Ofman testified to the efficiencies that would arise from the Transaction.

Response to Finding No. 1612

The proposed finding is vague and unsupported. This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have simply averred that Dr. Ofman testified to vague, undescribed efficiencies and provided no cite or reference to any piece of evidence. This Court should disregard the proposed finding as unsupported.

1613. *Acceleration of Market Access to Galleri.* Dr. Ofman testified that Galleri is available in the market as a laboratory-developed test (LDT), but to achieve GRAIL's goal to provide broad access to Galleri to as many adult Americans as possible, GRAIL will not be able to get Medicare reimbursement or large U.S. payor coverage without FDA approval. (Ofman (GRAIL) Tr. 3317–20.)

Response to Finding No. 1613

The proposed finding is misleading and unsupported. [redacted] The proposed finding is misleading and unsupported, however, because this fact does not demonstrate or support "acceleration of market access to Galleri." Moreover, nowhere in the cited testimony does Dr. Ofman discuss acceleration of market access to Galleri. Therefore, this Court should disregard the proposed finding.

1614. [redacted]

Response to Finding No. 1614

[redacted]

1615. Dr. Ofman testified that GRAIL is working on its PMA application submission to the FDA (Ofman (GRAIL) Tr. 3324); [redacted]

Response to Finding No. 1615

1616. Dr. Ofman testified that he is confident that Illumina will help GRAIL accelerate its FDA approval process (Ofman (GRAIL) Tr. 3455–56);

Response to Finding No. 1616

[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

[redacted]

[redacted].}

1616.1 [redacted]

Response to Finding No. 1616.1

[redacted]

[redacted]

[redacted]

1617. *Acceleration of Galleri's International Availability.* Dr. Ofman testified that partnering with Illumina would enable GRAIL's mission and vision to be accelerated by getting to scale quickly and getting GRAIL's breakthrough technology into the hands of doctors and their patients on a global scale as soon as possible (Ofman (GRAIL) Tr. 3283); and that GRAIL will not be able to make its test accessible to as many patients as it wants to reach without Illumina, because GRAIL's ability to achieve its aspiration will not only be accelerated, but also fortified, by being part of a company with the magnitude and the capabilities of Illumina. (Ofman (GRAIL) Tr. 3307–08, 3320.)

Response to Finding No. 1617

Dr. Ofman's statements were revealed at trial to be unsupported, self-serving speculation that were not based on any relevant personal knowledge and were uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of Dr. Ofman's testimony as well as lack of foundation or explanation for Dr. Ofman's base conjecture, this proposed finding of fact should be disregarded.

First, the proposed finding mischaracterizes Dr. Ofman's testimony by omitting his actual language, which highlights the speculative and unsubstantiated nature of his statements. For example, Dr. Ofman did not state that Illumina *would* accelerate Grail's timeline, but rather that

he "firmly *believe[s]* that the time will be greatly accelerated." (Ofman (Grail) Tr. 3308 (emphasis added)). He did not state that he had knowledge that Illumina *would* accelerate Grail's commercial scaling, but rather testified that partnering being acquired by Illumina "*could* accelerate the scale that we need . . . ." ." (Ofman (Grail) Tr. 3320 (emphasis added)).

[redacted]

1618. Dr. Ofman testified that, but for the lawsuit, Illumina and GRAIL would have begun to explore integration in affairs, quality management system (QMS), compliance, clinical development and medical affairs areas. (Ofman (GRAIL) Tr. 3457–58.)

Response to Finding No. 1618

Complaint Counsel does not disagree that Illumina and Grail have not even "begun to explore integration in affairs, quality management system (QMS) compliance, clinical development and medical affairs areas." The proposed finding's attribution of this state of affairs to "the lawsuit," however is vague because the term "the lawsuit" is ambiguous and undefined. To the extent the lawsuit refers to the current administrative proceeding, the proposed finding is misleading and incorrect.

Respondents chose to close the Acquisition in August 2021 despite a standstill order from the European Commission; when they did so, they promised to hold Grail separate from Illumina, meaning that Grail "will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis." (deSouza (Illumina) Tr. 2463; [redacted]

[redacted] These commitments are not related to the current administrative proceeding.

The parties are not subject to a preliminary injunction in the United States. Moreover, Respondents cite no order of this Court that prevents them from engaging in premerger integration planning. In the United States, the level of coordination permitted during the premerger process is governed by the federal antitrust laws. The parties are prohibited by the federal antitrust laws from engaging in collective actions that adversely affect competition. (*See, e.g.,* 15 U.S.C. § 1 (prohibiting agreements that unreasonably restrain trade); 15 U.S.C. § 45 (prohibiting unfair methods of competition); 15 U.S.C. § 2 (prohibiting monopolization, attempts to monopolize, and conspiracies to monopolize). To the extent that Respondents have made the independent determination that any form of premerger integration planning would adversely affect competition and violate the antitrust laws, that is their own determination and not the result of any specific prohibition related to the instant administrative proceeding. Therefore, this Court should disregard the proposed finding.

3. **Aaron Friedin**

a. Background

1619. Aaron Freidin is the Senior Vice President of Finance at GRAIL. (Freidin (GRAIL) Tr. 2964.)

Response to Finding No. 1619

Complaint Counsel does not disagree with the proposed finding.

1620. Mr. Freidin assumed the role of Senior Vice President of Finance in January 2021. (Friedin (GRAIL) Tr. 2964.) As Senior Vice President of Finance, Freidin oversees

accounting organization, financial planning and analysis. (Freidin (GRAIL) Tr. 2967.) He also oversees investor relations, corporate development, strategy, procurement, facilities and IT. (Freidin (GRAIL) Tr. 2967.) His primary responsibility is to roll up GRAIL's forecast for the year, develop the budget, assess headcount needs, put together GRAIL's long-range plan and understand and guide GRAIL's high-level strategy. (Freidin (GRAIL) Tr. 2967.)

Response to Finding No. 1620

The proposed finding is vague and confusing. The proposed finding is vague because the phrase "roll up GRAIL's forecast" is undefined and it is unclear what specific activity or activities "rolling up" is intended to describe. The proposed finding is confusing because the sentence that purports to describe Mr. Freidin's "primary responsibility" lists five separate responsibilities. Therefore, this Court should disregard the proposed finding.

1621. Friedin has also held the positions of Vice President of Finance, Senior Director of Finance and Director of Finance at GRAIL. (Freidin (GRAIL) Tr. 2964.)

Response to Finding No. 1621

Complaint Counsel has no specific response to the proposed finding.

1622. Prior to joining GRAIL, Freidin spent about two to three years at Counsyl, an NGS lab in South San Francisco; spent a couple of years at Cepheid, a molecular diagnostic public company; and spent the first ten years of his career at PricewaterhouseCoopers in San Jose as a senior manager in the audit practice, specifically in the semiconductor and life science area. (Freidin (GRAIL) Tr. 2965–66.)

Response to Finding No. 1622

Complaint Counsel has no specific response to the proposed finding.

b. Testimony

1623. The Galleri Test. Mr. Freidin testified that GRAIL launched Galleri in the U.S. in early June 2021; it is not commercially available outside the U.S.; and, as of the date of his testimony, Galleri had sold around 3,000 tests, which constitutes less than a tenth or a hundredth of a percent of the total addressable market of 108 million. (Freidin (GRAIL) Tr. 2968–69.)

Response to Finding No. 1623

Mr. Freidin's testimony that Galleri's sales as of the date of trial "constitutes less than a tenth or a hundredth of a percent of the total addressable market of 108 million" is confusing and

incomplete. The proposed finding is confusing because Mr. Freidin testified that Grail's estimated addressable market of 108 million individuals represents a per-year estimate. (Freidin (Grail) Tr. 1968). Grail launched Galleri in June and Mr. Freidin testified in September. Thus, Mr. Freidin's calculation is not based on a full year of Galleri sales. [redacted] Galleri's rate of sales will logically increase over the course of the year. It is thus not clear what, if anything, Mr. Freidin's calculation based on the first few months of Galleri sales is intended to signify. Therefore, this Court should disregard the proposed finding.

1624. Alleged Foreclosure. Mr. Freidin testified to facts that show that Illumina will continue to have an incentive to support other test developers. Specifically, Mr. Freidin testified that GRAIL expects to penetrate only about 13 to 16 percent of the market in the next ten years because GRAIL expects there to be multiple winners in the market. (Freidin (GRAIL) Tr. 2970.)

Response to Finding No. 1624

Complaint Counsel does not disagree that Mr. Freidin testified that Grail "expect[s] there to be multiple winners" in the market. Respondents' interpretation of that testimony, however, is incorrect as a matter of economics. [redacted]

[redacted]

Mr. Freidin testified that Grail has defined a total addressable market for Galleri of 108 million individuals: "the Galleri test is designed to work with people to the ages of 50 and 80, which we estimate to be about 108 million people in the U.S." (Freidin (Grail) Tr. 2968)). Therefore, this Court should disregard the proposed finding.

> **Q. Do you have a projection of what portion of that total addressable market you expect to someday achieve sales to?**
> A. Yeah. So based off of our 2020 long-range plan, which was our best estimate at the time, prior to our launch, and so on, we estimated that in the next ten years we would get to between 13 and 16 percent market penetration in our base case of that 108 million.
>
> **Q. By when?**
> A. By 2030. Yeah. I believe it's a ten-year plan. 2030 or 2031, so...
>
> **Q. Why are you projecting only 13 to 16 percent?**
> A. You know, we expect this space to be – have multiple players in it. It's feedback that we've heard from, you know, our -- our advisors, our investors, and so on, and just looking at the amount of investment in the space, we expect there to be multiple winners and it not be a winner-take-all type market.

(Freidin (Grail) Tr. 2969-2970). Mr. Freidin's testimony is specifically about the addressable market for Galleri. Mr. Freidin explains that the presence of "multiple players" and "multiple winners" is why Grail was only projecting 13-16 percent. Indeed, Freidin is pointing to the presence of other companies as *the reason* why Grail's sales projections are "only 13-16 percent." These "multiple players" and "multiple winners" must be substitutable with Galleri to affect Galleri's sales. To the extent that another product is a "complement" to Galleri, that product would, by definition, not affect Galleri's sales. As Respondents' own expert testified, if a test is a "complement" to Galleri, then "foreclosure of [the other test] would cause no material diversion to Galleri." (RX6000 (Carlton Trial Dep. at 24, 26–27)). When asked why Grail was projecting "only 13 to 16 percent," Mr. Freidin could have talked about barriers to MCED adoption or to other Galleri-specific factors; but he did just the opposite and attributed Grail's

low share to the fact that Grail "expect[s] this space to be – have multiple players in it." (Freidin (Grail) Tr. 2970)).

Further, the first sentence of the proposed finding is uncited, improper, misleading, and should be rejected by this Court. First, the first sentence of this proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of the first sentence of their proposed finding, in direct contravention of this Court's Order. Second, the first sentence of the proposed finding is misleading. Respondents claim that "Mr. Freidin testified to facts," and then only supply one purported fact. Third, the proposed finding is vague. Respondents do not define the term "other test developers," which is ambiguous and could refer to MCED test developers or some other type of test developer.

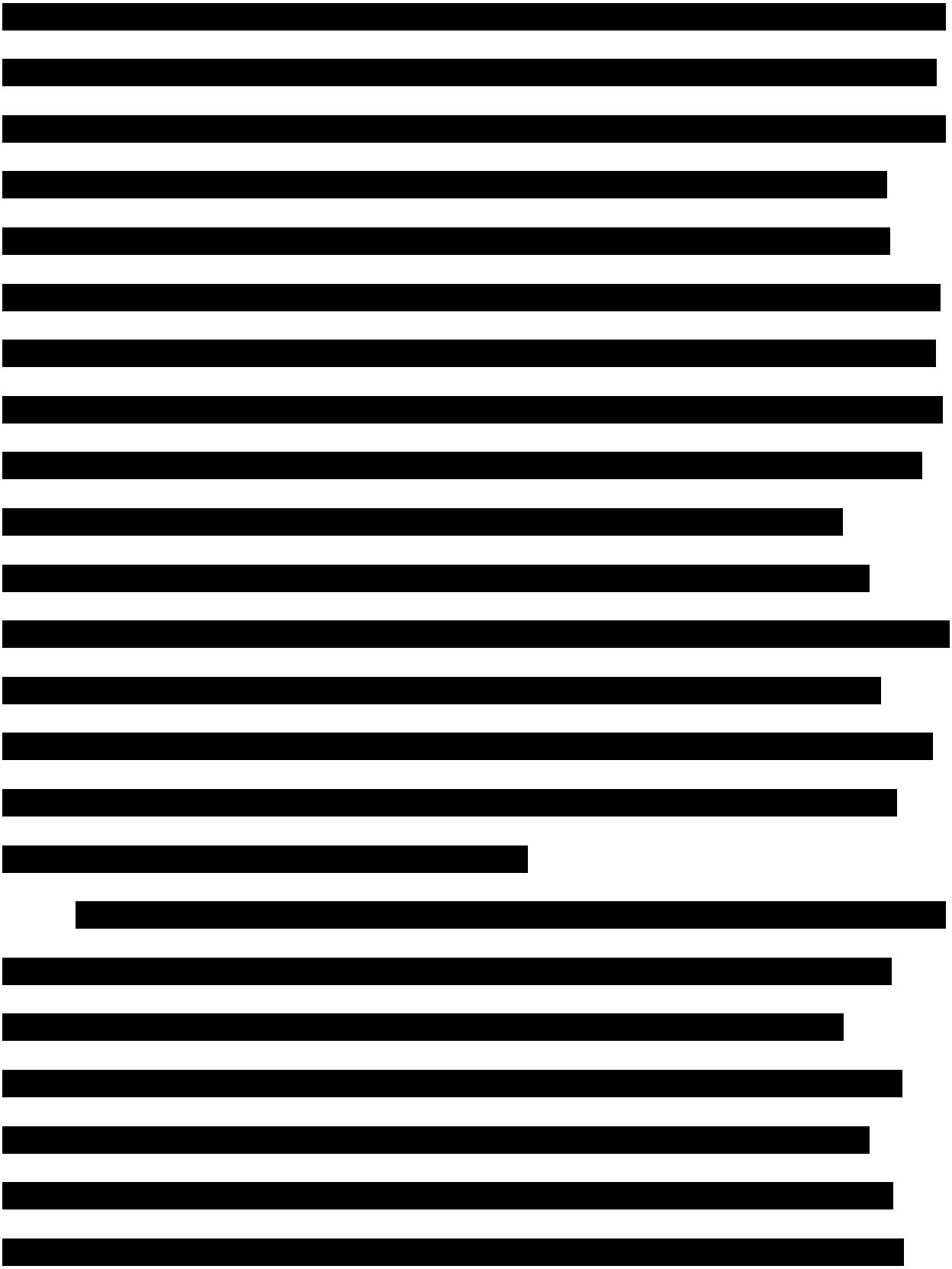
The second sentence of Respondents' proposed finding is unreliable. Rather than referencing evidence or testimony to substantiate the very specific claim that "GRAIL expects to penetrate only about 13 to 16 percent of the market in the next ten years because GRAIL expects there to be multiple winners in the market," Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

1625. [redacted]

[redacted]

Response to Finding No. 1625

[redacted]



[redacted]

[redacted]

1626. The Transaction. As Vice President of Finance, Mr. Freidin was one of the four people at GRAIL who was deeply involved in negotiations over the transaction; he focused primarily on the financial implications of the transaction. (Freidin (GRAIL) Tr. 2972.)

Response to Finding No. 1626

The proposed finding is vague because the term "deeply involved" is undefined. The phrase "negotiations over the transaction" is also ambiguous. It is unclear if the proposed finding is meant to suggest that Mr. Freidin participated in direct negotiations with Illumina or just in internal "negotiations" at Grail related to Illumina's acquisition offer. Therefore, this Court should disregard the proposed finding.

1627. Mr. Freidin testified that, from a financial perspective, he concluded that GRAIL should be acquired by Illumina because it would accelerate the saving of lives, accelerate funding for GRAIL, be a great return for shareholders, derisk GRAIL's business and eliminate the royalty in GRAIL's supply agreement with Illumina. (Freidin (GRAIL) Tr. 2972–73.)

Response to Finding No. 1627

The proposed finding is unreliable. For support, Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

Mr. Freidin admitted at trial that he lacks a basis for claims related to supposed "acceleration" of Galleri. Mr. Freidin testified at trial that Grail did not prepare its own deal

model, (Freidin (Grail) Tr. 3140) and in fact "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141). When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141). Mr. Freidin conceded that Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52). Moreover, Mr. Freidin admitted that Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail) Tr. 3145).

[redacted] Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

The proposed finding is vague, confusing, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "accelerate" (in multiple instances), "a great return for shareholders," and

"derisk." In particular, the term "a great return for shareholders" is ambiguous in that "great" communicates no factual information at all and Respondents fail to identify for whose shareholders there would be a "great return." Further, to the extent Respondents suggest that Grail was in jeopardy financially or otherwise would have difficulty raising capital without the Illumina transaction, this is against the weight of substantial evidence demonstrating that Grail is able to raise funds as an independent company and had [redacted]

Moreover, the merger with Illumina is not the only way for Grail to have eliminated the royalty. As demonstrated by record evidence, there are multiple reasons why the parties may not have eliminated the royalty prior to their agreement to merge, and thus, the absence of its pre-merger elimination is not "proof" of merger-specificity. Prior to the Acquisition, [redacted]

[redacted] however, as Illumina and Grail began discussions about a potential merger later that year. Therefore, the only conclusion to be inferred from the fact that the royalty had not been eliminated at the time of the merger agreement is merely that the parties had not yet discussed doing so; that does not mean the elimination of the royalty is merger-specific. Therefore, this Court should disregard the proposed finding.

1628. Mr. Freidin testified that the best way to accomplish the goal of accelerating broad-scale adoption of Galleri is the acquisition of GRAIL because Illumina has greater expertise than GRAIL. (Freidin (GRAIL) Tr. 2971.)

Response to Finding No. 1628

The proposed finding is vague and unreliable. The proposed finding is vague because the term "greater expertise" is undefined; it is not clear to what specific expertise, if any, the proposed finding purports to refer or whether Illumina has such expertise.

The proposed finding is inherently unreliable. For support, Respondents cite only to the self-serving speculation of a Grail executive, uncorroborated by any ordinary course documents or analysis. Mr. Freidin admitted at trial that he lacks a basis for claims related to supposed "acceleration" of Galleri. Mr. Freidin testified at trial that Grail did not prepare its own deal model, (Freidin (Grail) Tr. 3140) and in fact "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141). When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141). Mr. Freidin conceded that Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52). Moreover,

Mr. Freidin admitted that Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail) Tr. 3145).

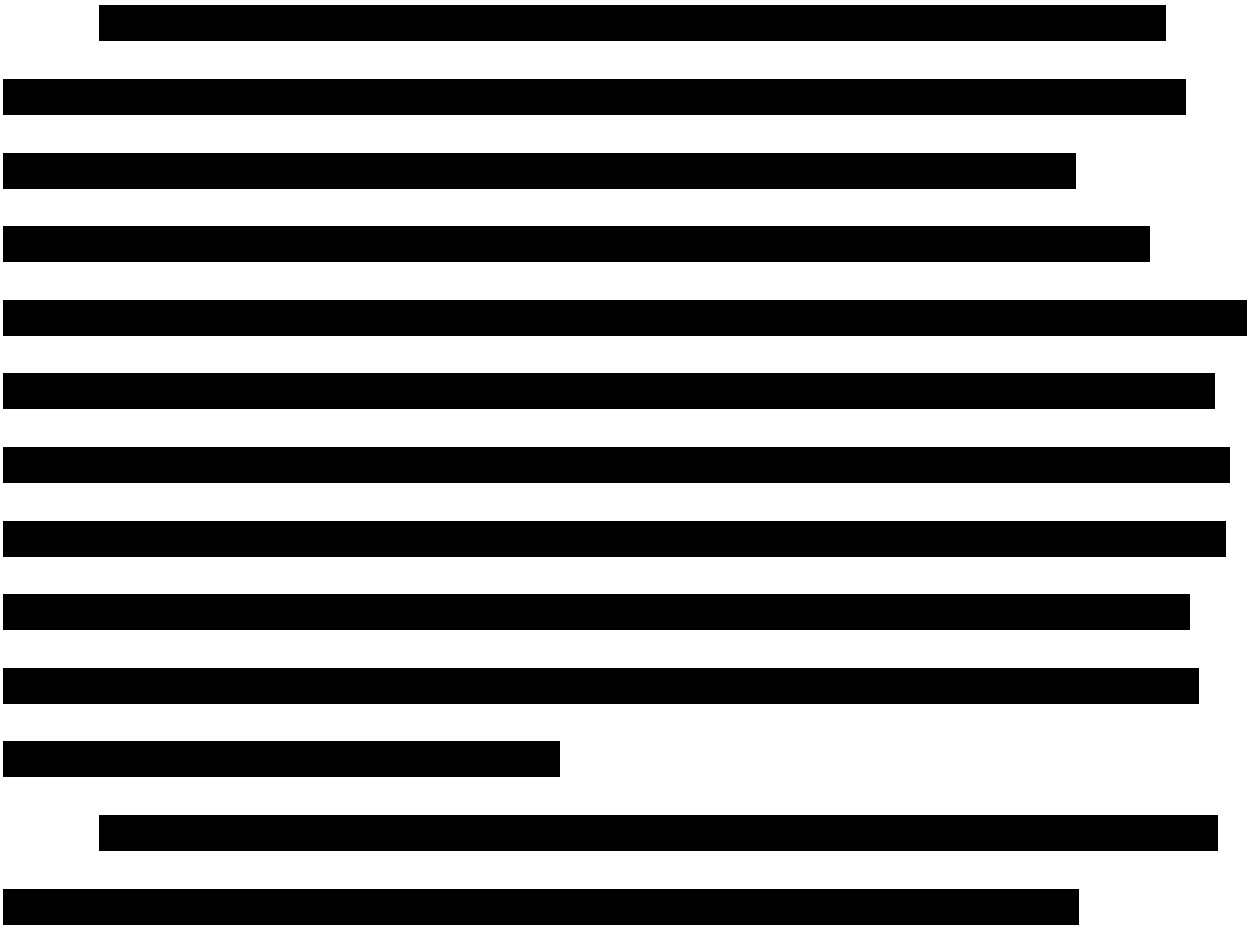
[redacted] Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

1629. Efficiencies. Mr. Freidin testified that the reunion of Illumina and GRAIL would lead to at least seven benefits which led him to recommend acceptance of the Transaction: elimination of the royalty (Freidin (GRAIL) Tr. 2974); accelerating FDA, Medicare and public payor approval; accelerating private payor partnerships; securing long-term funding; accelerating commercialization at scale (Freidin (GRAIL) Tr. 3000–01); increased laboratory operation capabilities and automation and accelerating international expansion. (Freidin (GRAIL) Tr. 2974.) He also testified that the Transaction would save lives. (Freidin (GRAIL) Tr. 2999.)

Response to Finding No. 1629

The proposed finding is unreliable and speculative. For support, Respondents cite only to the self-serving speculation of a Grail executive, uncorroborated by any ordinary course documents or analysis. Mr. Freidin admitted at trial that he lacks a basis for claims related to claimed efficiencies from the proposed transaction. Mr. Freidin testified at trial that Grail did

not prepare its own deal model, (Freidin (Grail) Tr. 3140) and in fact "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141). When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141). Mr. Freidin conceded that Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52). Moreover, Mr. Freidin admitted that Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail) Tr. 3145).



1629.1 As Freidin explained: "We knew that we would have to go out and to raise a significant amount of capital and more than -- and more than once over the, you know, next five or six years, and so by Illumina acquiring us, you know, we don't have to worry about that anymore. Illumina is a, you know, multibillion-dollar, profitable

> business that generates cash flows. And if they ever ran out of cash flows or we needed to spend more, they have successfully raised debt and done other offerings, so it -- in my view, it derisked our capital needs and accelerated our ability to put capital to work immediately and was another positive benefit of the acquisition." (Freidin (GRAIL) Tr. 3000.)

Response to Finding No. 1629.1

The proposed finding is vague, unreliable, and should be rejected by this Court. The proposed finding is vague. Respondents fail to define the terms "a significant amount of capital," "spend more," and "accelerated."

The proposed finding is also unreliable. Mr. Freidin has no basis to speak to the ability of Illumina to provide Grail with capital. Mr. Freidin has never worked at Illumina. (Freidin (Grail) Tr. 2965). [redacted] At trial, Mr. Freidin testified that he has not seen Illumina's financial model for the Illumina-Grail deal. (Freidin (Grail) Tr. 3139). It is unclear how Mr. Freidin has foundation to discuss Illumina's ability to raise capital and how Grail "[does not] have to worry about [raising a significant amount of capital] anymore."

Further, to the extent Respondents suggest that Grail was in jeopardy financially or otherwise would have difficulty raising capital without the Illumina transaction, this is against the weight of substantial evidence demonstrating that Grail is able to raise funds as an independent company and had [redacted] When Grail was acquired by Illumina, Grail had over $600 million in cash (Freidin (Grail) Tr. 3166-67). [redacted] And Morgan Stanley's Mr. Strom confirmed

that there is significant investor interest in the cancer diagnostics space. (Strom (Morgan Stanley) Tr. 3478). [redacted] Therefore, this Court should disregard the proposed finding.

1630. *Acceleration of Market Access to Galleri.* Mr. Freidin testified that a large inflection point to creating value and saving lives is broad reimbursement; he identified two ways in which the Transaction would accelerate market access: accelerating FDA, Medicare and public payor approval and accelerating private payor approval. (Freidin (GRAIL) Tr. 2979–82, 2987.)

Response to Finding No. 1630

The proposed finding is unreliable and against the weight of the evidence. For support, Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

Mr. Freidin admitted at trial that he lacks a basis for claims related to supposed "acceleration" of Galleri. Mr. Freidin testified at trial that Grail did not prepare its own deal model, (Freidin (Grail) Tr. 3140) and in fact "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141). When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141). Mr. Freidin conceded that Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52). Moreover, Mr. Freidin admitted that Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail) Tr. 3145).

[redacted] Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

1631. *Accelerating FDA, Medicare and Public Payor Approval.* Mr. Freidin testified that the population Galleri is addressing is between 50 and 80; that a large portion of that population is on public government pay; and that FDA, CMS and Medicare approval are the path to allow those individuals to afford the test. (Freidin Tr. 2979–81.) Mr. Freidin also testified that, in order to obtain Medicare approval, Galleri would need to be approved by CMS; CMS approval requires both FDA approval and showing that the cost-benefit analysis weighs in favor of paying for the test. (Freidin (GRAIL) Tr. 2981–82.)

Response to Finding No. 1631

The proposed finding is vague because the term "public government pay" is ambiguous. Complaint Counsel does not disagree that Mr. Freidin testified that Galleri is intended for individuals between the ages of 50 and 80. The proposed finding is vague because the phrase "the path to allow those individuals to afford the test" is ambiguous and appears to refer to the earlier statement about the population "on public government pay." Complaint Counsel does not disagree that FDA and CMS approval are important to enabling broad-based adoption of an MCED test. Complaint Counsel does not disagree that CMS approval to grant reimbursement for early cancer detection testing requires FDA approval and a cost-benefit analysis by CMS.

1632. Mr. Freidin testified that Illumina has demonstrated the ability to get tests approved by the FDA in the past; that Mr. deSouza provided details to GRAIL regarding Illumina's FDA capabilities, the team, the employees and their successes; that Mr. Friedin had also identified four examples in which Illumina had had success with the FDA: FDA-regulated NGS machines, FDA-cleared cystic fibrosis NGS test, FDA emergency use authorization for an NGS COVID-19 test and an NGS cancer therapy selection test; and that these examples substantiated what Mr. deSouza shared with GRAIL. (Freidin (GRAIL) Tr. 2984–85.)

Response to Finding No. 1632

The proposed finding is vague, confusing, and unreliable. The proposed finding is confusing because Respondents have improperly merged numerous proposed findings of fact together as a single composite "finding." Complaint Counsel objects to the composite nature of the proposed "finding" as improper. Respondents' combination of numerous largely unrelated statements is confusing and misleading to the extent Respondents intend to state one fact.

The proposed finding is vague because the phrase "ability to get tests approved by the FDA" in the past is ambiguous. It is unclear what Mr. Freidin means by the term "tests" or "approved." [redacted] The proposed finding is also vague because the phrase "provided details to GRAIL regarding Illumina's FDA capabilities" is non-specific and fails to

disclose any particular details or capabilities. The proposed finding is further vague because the term "identified" is not explained; it is not clear what Mr. Freidin specifically did to "identify . . examples in which Illumina had had success with the FDA." Moreover, the phrase "had success with the FDA" is itself vague; no specific definition of "success" is provided so it is unclear to what Mr. Freidin may be referring.

The proposed finding is unreliable. Mr. Freidin's statements about Illumina's supposed FDA capabilities were revealed at trial to be unsupported, self-serving speculation, not based on any relevant personal knowledge and uncorroborated by any ordinary course documents or analysis. [redacted]

[redacted]

To the extent the proposed finding is intended to suggest that Illumina possesses uniquely successful FDA regulatory capabilities, the proposed finding is against the weight of evidence.

[redacted]

[redacted]

Given the inherent unreliability of Mr. Freidin's testimony as well as lack of foundation or explanation for his testimony, this proposed finding of fact should be disregarded.

1633. Mr. Freidin explained that GRAIL has comparably fewer resources, a smaller regulatory team and no FDA-approved tests. (Freidin (GRAIL) Tr. 2985–86.)

Response to Finding No. 1633

The proposed finding is vague and confusing because it states that Grail has "comparatively fewer resources" and "a smaller regulatory team" but does not specify to who or what Grail is being compared. The proposed finding should be rejected.

[redacted]

[redacted]

1634. Mr. Freidin explained that the Transaction would accelerate and increase the chances of FDA approval from what GRAIL's internal capabilities and history with the FDA are. (Freidin (GRAIL) Tr. 2980, 2986.)

Response to Finding No. 1634

The proposed finding is vague, confusing, and unreliable. The proposed finding is confusing because the phrase "increase the chances of FDA approval from what GRAIL's

internal capabilities and history are" does not make grammatical sense. The proposed finding's use of the word "accelerate" is also ambiguous; it would appear to refer to accelerating the "chances" of FDA approval, which combines temporal and probabilistic concepts in a way that is confusing.

The proposed finding is unreliable. Mr. Freidin's statements about Illumina's supposed FDA capabilities were revealed at trial to be unsupported, self-serving speculation, not based on any relevant personal knowledge and uncorroborated by any ordinary course documents or analysis.

[redacted]

Additionally, Mr. Freidin lacks foundation to comment on the possibility of FDA approval acceleration. Mr. Freidin testified at trial that Grail's FP&A team, which Mr. Freidin leads, did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145). [redacted]

To the extent the proposed finding is intended to suggest that Illumina possesses uniquely successful FDA regulatory capabilities, the proposed finding is against the weight of evidence.

[redacted]

[redacted] Given the inherent unreliability of Mr. Freidin's testimony as well as lack of foundation or explanation for his testimony, this proposed finding of fact should be disregarded.

1635. *Accelerating Private Payor Partnerships.* Mr. Freidin explained that millions of lives targeted by Galleri are covered by commercial or private insurance (Freidin (GRAIL) Tr. 2987); that 68% of individuals between 18 and 64 are covered by private and commercial insurance (Freidin (GRAIL) Tr. 2988); that no public or private payors currently reimburse for Galleri (Freidin (GRAIL) Tr. 2992); that FDA approval alone will not guarantee private coverage (Freidin (GRAIL) Tr. 2993); that recommendations of the USPSTF, commercial payors and other guideline bodies will be required to achieve broad private payor reimbursement (Freidin (GRAIL) Tr. 2993-94); and that the large addressable market means that private payors will require significant evidence before providing for reimbursement. (Freidin (GRAIL) Tr. 2996–97.)

Response to Finding No. 1635

The proposed finding is confusing, misleading, and unsupported. The proposed finding is confusing because Respondents have improperly merged numerous proposed findings of fact together as a single composite "finding." Complaint Counsel objects to the composite nature of

the proposed "finding" as improper. Respondents' combination of numerous largely unrelated statements is confusing and misleading to the extent Respondents intend to state one fact.

The proposed finding is misleading and unsupported because it includes the heading "accelerating private payor partnerships," but cites no testimony or other evidence that relates to any purported or claimed "acceleration" of any "private payor partnerships." Therefore, this Court should disregard the proposed finding.

1636. Mr. Freidin explained that GRAIL has no experience obtaining private insurer reimbursement, has a small team and lacks resources to pursue private payor reimbursement. (Freidin (GRAIL) Tr. 2997–98.)

Response to Finding No. 1636

The proposed finding is vague, confusing, misleading, unreliable, and against the weight of the evidence. The proposed finding is vague because the phrases "small team" and "lacks resources" are ambiguous and undefined. The proposed finding is vague because the term "private insurer" is undefined and confusing because the proposed finding uses both the terms "private insurer reimbursement" and "private payor reimbursement."

The proposed finding is unreliable. For support, Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

The proposed finding's suggestion that Grail's regulatory group lacks reimbursement experience is misleading and against the weight of the evidence. Grail's Dr. Ofman has worked on bringing technology to patients for about 25 years. (Ofman (Grail) Tr. 3449). Dr. Ofman and Grail's Head of Government Affairs, Rodger Currie, refined Grail's reimbursement strategy to accelerate opportunities for coverage through Medicare modernization. (Ofman (Grail) Tr. 3449). Dr. Ofman testified that Grail has brought in a highly skilled group of professionals,

including Mr. Currie, to help achieve Grail's reimbursement strategy. (Ofman (Grail) Tr. 3449). Grail has always made its reimbursement strategy a priority. (Ofman (Grail) Tr. 3449-50). In Dr. Ofman's judgment, Grail's reimbursement strategy has received the attention it needs. (Ofman (Grail) Tr. 3450).

To the extent that the proposed finding's claim that Grail "lacks resources to pursue private payor reimbursement" is meant to suggest that Grail lacks the ability to pursue commercialization of Galleri, the proposed finding is also misleading. Grail is, in fact, actively pursuing commercialization of Galleri through agreements with private payors. Grail is currently focused on marketing its Galleri test to large physician groups, health systems, and employers. (Freidin (Grail) Tr. 2995; Della Porta (Grail) Tr. 456-57). Grail has approximately 30 to 40 people on its sales team. (Della Porta (Grail) Tr. 459). [redacted]

[redacted]

Additionally, Grail is actively marketing Galleri to concierge practices and had successfully executed deals with approximately 15 concierge practices representing over 500,000 patients (*see* Della Porta (Grail) Tr. 464). Grail is also marketing Galleri to self-insured employers. [redacted] Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded. For all the above reasons, the proposed finding should be disregarded as unfounded, unreliable, and against the weight of the evidence.

1637. Mr. Freidin also testified that Illumina has capabilities and expertise as well as successful partnerships with government agencies and private payors, including Harvard Pilgrim, Blue Cross Blue Shield and the State of Michigan. (Freidin (GRAIL) Tr. 2999.)

Response to Finding No. 1637

The proposed finding is vague, misleading, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "capabilities," "expertise," and "successful partnerships." In particular, the terms "capabilities" and "expertise" are vague and

it's unclear what Illumina brings to the table with respect to this claim; certainly, Mr. Freidin did not testify with specificity regarding these claims.

The proposed finding is unreliable. Mr. Freidin clearly lacks foundation to discuss whether "Illumina has capabilities and expertise as well as successful partnerships with government agencies and private payors." Mr. Freidin has never worked at Illumina. (Freidin (Grail) Tr. 2965). With respect to Illumina's ability to accelerate Galleri's FDA approval, [redacted]

Lastly, the proposed finding is misleading insofar as it implies that any Illumina has "capabilities and expertise as well as successful partnerships with government agencies and private payors" and that any such "capabilities [or] expertise" will accelerate Galleri's FDA approval or market access. Such an implication is against the weight of the evidence, which demonstrates Illumina did not, in the ordinary course, anticipate accelerating Grail's regulatory approval or payer adoption [redacted]

[redacted] The evidence shows that the relevance of any experience Illumina has achieving reimbursement is questionable at best. Therefore, this Court should disregard the proposed finding.

1638. Mr. Freidin testified that Illumina is likely to derisk and accelerate GRAIL's private payor acceptance and reimbursement, which will save more lives. (Freidin (GRAIL) Tr. 2999.)

Response to Finding No. 1638

The proposed finding is vague, unreliable, and against the weight of the evidence. The proposed finding is vague because the tern "derisk" is undefined. Fundamentally, the proposed finding is unreliable. For support, Respondents cite only to the self-serving testimony of a Grail executive that is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

Mr. Freidin admitted at trial that he lacks a basis for claims related to supposed "acceleration" of Galleri. Mr. Freidin testified at trial that Grail did not prepare its own deal model, (Freidin (Grail) Tr. 3140) and in fact "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141). When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141). Mr. Freidin conceded that Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52). Moreover, Mr. Freidin admitted that Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail)

Tr. 3145).

[redacted] Given the inherent unreliability of this testimony, this proposed finding of fact should be disregarded.

1639. *Securing Long-Term Funding.* Mr. Freidin testified that as part of GRAIL's long-range plan, the company estimated the amount of capital they would need to be self-sufficient and fund themselves; the company estimated it would need several large raises over the next five or six years; and that Illumina's acquisition removed that concern because Illumina is a multibillion-dollar, profitable business that generates cash flows and can raise money through debt and other offerings. (Freidin (GRAIL) Tr. 3000.)

Response to Finding No. 1639

The proposed finding is vague. Respondents fail to define the terms "several large raises" and "other offerings." The proposed finding is unreliable. Rather than referencing evidence or testimony to substantiate the proposed finding (e.g., demonstrating that Grail "estimated it would need several large raises over the next five or six years" or that Illumina "can raise money through debt and other offerings"), Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. Further, the proposed finding is also unreliable because Mr. Freidin lacks foundation to testify about Illumina's ability to "raise money through debt and other offerings."

Mr. Freidin has never worked at Illumina. (Freidin (Grail) Tr. 2965). [redacted] It is therefore unclear how, if at all, Mr. Freidin could determine that Illumina "can raise money through debt and other offerings.

Further, to the extent Respondents suggest that Grail would have difficulty raising capital without the Illumina transaction, this is against the weight of substantial evidence demonstrating that Grail is able to raise funds as an independent company and had [redacted] When Grail was acquired by Illumina, Grail had over $600 million in cash (Freidin (Grail) Tr. 3166-67). [redacted] And Morgan Stanley's Mr. Strom confirmed that there is significant investor interest in the cancer diagnostics space. (Strom (Morgan Stanley) Tr. 3478). [redacted] Therefore, this Court should disregard the proposed finding.

1640. *Elimination of the Royalty.* [redacted]

Response to Finding No. 1640

The proposed finding is vague. Respondents fail to define the terms "limited access," "lower prices," "increased access," and "decrease the price." These terms are vague and ambiguous and do not communicate any factual information about the "access" to or price of Galleri. Rather than referencing evidence or testimony to substantiate the proposed finding (e.g., evidencing how the royalty limited access, or how its elimination would "lead to lower prices and increased access"), Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Further, the proposed finding is misleading, insofar as it implies that the benefits to Grail of eliminating the royalty will be passed on to consumers. [redacted]

Moreover, the merger with Illumina is not the only way for Grail to have eliminated the royalty. As demonstrated by record evidence, there are multiple reasons why the parties may not have eliminated the royalty prior to their agreement to merge, and thus, the absence of its pre-merger elimination is not "proof" of merger-specificity. Prior to the Acquisition, [redacted]

[redacted] These are but two of many possible ways in which Grail could have eliminated the royalty "without the merger."

[redacted] however, as Illumina and Grail began discussions about a potential merger later that year. Therefore, the only conclusion to be inferred from the fact that the royalty had not been eliminated at the time of the merger agreement is merely that the parties had not yet discussed doing so; that does not mean the elimination of the royalty is merger-specific and the weight of the evidence indicates that it is not merger-specific. Therefore, this Court should disregard the proposed finding.

1641. [redacted]

Response to Finding No. 1641

The proposed finding is vague, confusing, unreliable, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the term "these options," "economic give," and "too massive." The proposed finding is also confusing, in that it is unclear

how the removal of a royalty payment would be "too massive" of an "economic give" for Grail to attempt. The proposed finding is unreliable. Rather than referencing evidence or testimony to substantiate the very specific claims regarding "scenarios" Morgan Stanley ran or conclusions Morgan Stanley reached, Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

To the extent Respondents suggest that the merger with Illumina was the only way for Grail to have eliminated the royalty, the proposed finding is against the weight of the evidence. As demonstrated by record evidence, there are multiple reasons why the parties may not have eliminated the royalty prior to their agreement to merge, and thus, the absence of its pre-merger elimination is not "proof" of merger-specificity. Prior to the Acquisition, [redacted]

[redacted] however, as Illumina and Grail began discussions about a potential merger later that year. [redacted] For the reasons stated above, this Court should disregard the proposed finding.

1642. *Supply Chain and Operational Efficiencies/Acceleration Commercialization at Scale.* Mr. Freidin testified that GRAIL is an R&D company with limited commercial sales experience and capabilities (Freidin (GRAIL) Tr. 3000–02); that [redacted]

Response to Finding No. 1642

The proposed finding is vague, unreliable, misleading, and should be disregarded by this Court. The proposed finding is vague because Respondents fail to define the terms "limited commercial sales," "limited commercial sales . . . capabilities," "difficulties," "negative patient and physician experiences," and "difficulties with software." In particular, the term "limited" is a relative term and communicates no factual information.

The proposed finding is unreliable for two reasons. First, rather than referencing

evidence or testimony to substantiate the proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Second, the proposed finding is unreliable because Mr. Freidin is not involved in any areas relating to whether [redacted] and does not have foundation to support such a "fact." Mr. Freidin is not in charge of Grail's product development team, competitive intelligence team, regulatory team, medical affairs team, quality team, market access team, clinical studies team, lab operations team, government affairs team, or Grail's communication with payers. (Freidin (Grail) Tr. 3136-37). Mr. Friendin's opinions regarding whether [redacted] lack foundation, are unreliable, and should be disregarded by this Court. [redacted] Therefore, this Court should disregard the proposed finding.

1643. Mr. Freidin testified that Illumina is a multibillion-dollar, international company that sells products in various sections and has demonstrated capabilities and skill sets that GRAIL needs to build; that Illumina has a large software engineering function that has built similar systems to what GRAIL needs; and that Illumina has the ability to execute with vendors and customers. (Freidin (GRAIL) Tr. 3000–04, [redacted]

Response to Finding No. 1643

The proposed finding is vague, unreliable, and this Court should therefore disregard the proposed finding. The proposed finding is vague because Respondents fail to define the terms "various sections," "capabilities," "skill sets," "large," "similar systems," and "ability to

execute."

The proposed finding is unreliable for at least two reasons. First, rather than referencing evidence or testimony to substantiate the very specific claim that "Illumina has a large software engineering function that has built similar systems to what GRAIL needs," Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Second, the proposed finding is unreliable because Mr. Freidin clearly lacks foundation to discuss whether "Illumina has a large software engineering function that has built similar systems to what GRAIL needs." Mr. Freidin has never worked at Illumina. (Freidin (Grail) Tr. 2965). With respect to Illumina's ability to accelerate Galleri's FDA approval, [redacted] Given how little Mr. Freidin knows about Illumina's FDA processes, it is unclear what foundation he has to speak about Illumina's other "capabilities."

Moreover, with respect to Grail, Mr. Freidin is not involved in any areas relating to whether "Illumina has a large software engineering function that has built similar systems to what GRAIL needs," and does not have foundation to support such a "fact." Mr. Freidin is not in charge of Grail's product development team, competitive intelligence team, regulatory team, medical affairs team, quality team, market access team, clinical studies team, lab operations team, government affairs team, or Grail's communication with payers. (Freidin (Grail) Tr. 3136-37). Mr. Freidin's opinions regarding whether "Illumina has a large software engineering function that has built similar systems to what GRAIL needs," lack foundation, are unreliable, and should be disregarded by this Court.

[redacted] Therefore, this Court should disregard the proposed finding

1644. Mr. Freidin testified that, in order to commercialize Galleri, GRAIL will need commercial sales experience and laboratory operations and automation, which includes high capacity manufacturing, software and customer management and quality control systems. (Freidin (GRAIL) Tr. 3002–04.)

Response to Finding No. 1644

The proposed finding is vague, unreliable, and relies solely on the self-serving testimony of Mr. Freidin. The proposed finding is vague because the phase "in order to commercialize Galleri" is ambiguous, and the phrases "laboratory operations," "automation," "high capacity manufacturing," "software," and "customer management and quality control systems" are undefined. To the extent that the proposed finding suggests that Grail is unable to commercialize Galleri, the finding is incorrect. Grail is already commercializing Galleri. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1645. Mr. Freidin explained that, with regard to commercial sales experience, GRAIL only has three to four months of experience, whereas Illumina is a successful multibillion-dollar, international company with multiple products. (Freidin (GRAIL) Tr. 3004.) Mr. Freidin testified that Illumina will enable GRAIL to commercialize much faster than it would on its own. (Freidin (GRAIL) Tr. 3004.)

Response to Finding No. 1645

The proposed finding is vague, unreliable, speculative, misleading, and against the weight of substantial evidence to the extent that Respondents suggest that Illumina's claimed supply chain and operational efficiencies are cognizable. The proposed finding is vague because the term "commercialize" is ambiguous and undefined. The proposed finding is unreliable and speculative: to support about Illumina's supposed capabilities, Respondents cite only to the self-serving speculation of a Grail executive, uncorroborated by any ordinary course documents or analysis.

Mr. Freidin admitted at trial that he lacks a basis for claims related to claimed efficiencies from the proposed transaction. Mr. Freidin testified at trial that Grail did not prepare its own deal model, (Freidin (Grail) Tr. 3140) and in fact "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141). When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141). Mr. Freidin conceded that Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52).

Moreover, Mr. Freidin admitted that Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail) Tr. 3145).

[redacted]. Therefore, this Court should disregard the proposed finding.

1646. Mr. Freidin testified that GRAIL is focusing on a centralized lab process due to the complexity of Galleri and because it is the fastest way to process millions of tests (Freidin (GRAIL) Tr. 3006–07); that automation and lab processes are key to getting costs down and keeping quality high (Freidin (GRAIL) Tr. 3005–06); that this will bring the cost of Galleri down (Freidin (GRAIL) Tr. 3006); that [redacted] (Freidin (GRAIL) Tr. 3042) [redacted]

Response to Finding No. 1646

[redacted]

[redacted]

[redacted]

[redacted]

1647. Mr. Freidin explained that, in Illumina's work with the Verinata NIPT and other tests, Illumina has run labs, processed lots of tests and demonstrated that they have capabilities that can accelerate Galleri. (Freidin (GRAIL) Tr. 3007–08.)

Response to Finding No. 1647

The proposed finding is vague. Respondents fail to define the terms "other tests," "lots of tests," "capabilities," and "accelerate."

The proposed finding is unreliable. First, rather than referencing evidence or testimony to substantiate this proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Second, the proposed finding is unreliable because Mr. Freidin does not have foundation to speak on whether "Illumina has run labs, processed lots of tests and demonstrated that they have capabilities that can accelerate Galleri." Mr. Freidin has never worked at Illumina. (Freidin (Grail) Tr. 2965). With respect to Illumina's ability to accelerate Galleri's FDA approval, [redacted]

[redacted] Given how little Mr. Freidin knows about Illumina's "expertise" regarding regulatory approval in the United States, it is unclear what basis Mr. Freidin has regarding Illumina's "capabilities" internationally.

Moreover, with respect to Grail, Mr. Freidin is not involved in any areas relating to whether there would be any "benefits of the Transaction" and does not have foundation to support such a "fact." Mr. Freidin is not in charge of Grail's product development team, competitive intelligence team, regulatory team, medical affairs team, quality team, market access team, clinical studies team, lab operations team, government affairs team, or Grail's communication with payers. (Freidin (Grail) Tr. 3136-37). Mr. Freidin testified at trial that Grail's FP&A team, which Mr. Freidin leads, did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145). Mr. Frieden testified at trial that Grail's Medical Affairs and Regulatory teams did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145). Mr. Freidin's opinions regarding whether there would be any "international acceleration," lack foundation, are unreliable, and should be disregarded by this Court.

1648. *Expanding International Availability*. Mr. Freidin testified that GRAIL has been focused on the U.S. domestic market; that other than a study in the U.K. with the NHS, GRAIL's long-range plan ignores anything international; and that GRAIL does not have any international operations aside from 10–20 people in the U.K. to facilitate the NHS study. (Freidin (GRAIL) Tr. 3008.) [redacted]

Response to Finding No. 1648

The proposed finding is unreliable. First, rather than referencing evidence or testimony to substantiate this proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

[redacted] Thus, on its face, Respondents' claim that the transaction will accelerate the international expansion of Galleri is irrelevant as alleged benefits which occur outside the United States cannot offset competitive harm within the United States. And any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it.

Respondents produced no evidence regarding which specific countries the international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion would only be achieved through a merger with Illumina. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1649. Mr. Freidin testified that Illumina is a multinational billion-dollar company with multiple products and locations over the globe; that 50 percent of Illumina's revenues are international; and that Illumina's 10–K confirms its international reach. (Freidin (GRAIL) Tr. 3008–11.)

Response to Finding No. 1649

[redacted] The proposed finding is vague because the phrases "over the globe" and "international reach" are ambiguous and undefined, and because Mr. Freidin's reference to Illumina's 10-K is vague and lacks specificity. The proposed finding is unreliable: to support Illumina's supposed capabilities, Respondents cite only to the self-serving speculation of a Grail executive, uncorroborated by any ordinary course documents or analysis. Mr. Freidin's assertions about the contents of Illumina's 10-K does not constitute reliable testimony about the contents of Illumina's 10-K.

[redacted] Thus, on its face, Respondents' claim that the transaction will accelerate the international expansion of Galleri is irrelevant as alleged benefits which occur outside the United States cannot offset competitive harm within the United States. And any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the

likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it.

Respondents produced no evidence regarding which specific countries the international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion would only be achieved through a merger with Illumina. [redacted] Therefore, the proposed finding should be disregarded.

1650. Mr. Freidin testified that Illumina could accelerate Galleri internationally and that international acceleration can save lives around the world. (Freidin (GRAIL) Tr. 3008–10.)

Response to Finding No. 1650

The proposed finding is vague. Respondents fail to define the terms "accelerate," "internationally," and "international acceleration." In particular, Respondents fail to define any metric of "acceleration," nor do they provide any idea of what is meant by international—i.e., only certain ex-U.S. countries, only Europe, or all countries around the world.

The proposed finding is unreliable. First, rather than referencing evidence or testimony to substantiate this proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents

or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Second, the proposed finding is unreliable because Mr. Freidin does not have foundation to speak on whether "international acceleration" will result from the Transaction. Mr. Freidin has never worked at Illumina. (Freidin (Grail) Tr. 2965). With respect to Illumina's ability to accelerate Galleri's FDA approval, [redacted] Given how little Mr. Freidin knows about Illumina's "expertise" regarding regulatory approval in the United States, it is unclear what basis Mr. Freidin has regarding Illumina's "capabilities" internationally.

Moreover, with respect to Grail, Mr. Freidin is not involved in any areas relating to whether there would be any "benefits of the Transaction" and does not have foundation to support such a "fact." Mr. Freidin is not in charge of Grail's product development team, competitive intelligence team, regulatory team, medical affairs team, quality team, market access

team, clinical studies team, lab operations team, government affairs team, or Grail's communication with payers. (Freidin (Grail) Tr. 3136-37). Mr. Freidin testified at trial that Grail's FP&A team, which Mr. Freidin leads, did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145). Mr. Frieden testified at trial that Grail's Medical Affairs and Regulatory teams did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145). Mr. Freidin's opinions regarding whether there would be any "international acceleration," lack foundation, are unreliable, and should be disregarded by this Court.

[redacted] Thus, on its face, Respondents' claim that the transaction will accelerate the international expansion of Galleri is irrelevant as alleged benefits which occur outside the United States cannot offset competitive harm within the United States. And any attempt to link an alleged out-of-market efficiency to the relevant geographic market fails because Respondents do not establish the likelihood, magnitude, or merger-specificity of the claim, nor do they estimate any costs associated with achieving it.

Respondents produced no evidence regarding which specific countries the international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion would only be achieved through a

merger with Illumina. [redacted] Therefore, this Court should disregard the proposed finding.

1651. Mr. Freidin testified that: in considering whether to proceed with the Transaction or the capital markets, GRAIL considered the above efficiencies and whether they could be achieved through an IPO or other capital markets raises; GRAIL concluded that, even if it were to successfully raise more money, this would not come with the expertise and infrastructure Illumina has; GRAIL determined that capital market raises have the potential for significant delay; additional private capital raises were not an alternative because of the potential for delay; an IPO was not an alternative because it would not provide the benefits of the Transaction, including the elimination of the royalty, acceleration of FDA, Medicare and public payor approvals, securing long term funding, accelerating commercialization, lab operations and international expansion; and an IPO was unlikely to equal the $2 billion that GRAIL needed to get to break even. (Freidin (GRAIL) Tr. 3011–22.)

Response to Finding No. 1651

The proposed finding is confusing because Respondents have improperly merged numerous proposed findings of fact together as a single composite "finding." Complaint Counsel objects to the composite nature of the proposed "finding" as improper. Respondents' combination of numerous largely unrelated statements is confusing and misleading to the extent Respondents intend to state one fact.

The proposed finding is vague. Respondents fail to define the terms "the above efficiencies," "successfully raise more money," "expertise and infrastructure," "the potential for significant delay," "the potential for delay." "long term funding," "accelerating," and "unlikely." In particular, it is unclear which efficiencies Respondents refer to by "the above efficiencies"—

there are more than 1,600 findings above this one. It is also unclear what Respondents mean exactly by "the potential for significant delay" and "the potential for delay," or what the distinction is between the two.

The proposed finding is misleading and contradicted by Mr. Freidin's own testimony. Mr. Freidin testified that when Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141). Given this testimony, it is unclear how, as Respondents contend, "GRAIL considered the above efficiencies and whether they could be achieved through an IPO or other capital markets raises" (obviously depending on what Respondents mean by "the above efficiencies").

The proposed finding is unreliable. First, rather than referencing evidence or testimony to substantiate this proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Second, the proposed finding is unreliable because Mr. Freidin does not have foundation to speak on many of these subjects, including "the above efficiencies," (whatever those may be), whether Illumina even has "expertise and infrastructure," and whether there are "benefits of the Transaction . . . [including] acceleration of FDA, Medicare and public payor approvals, securing long term funding, accelerating commercialization, lab operations and international expansion; and an IPO was unlikely to equal the $2 billion that GRAIL needed to get to break even." Mr. Freidin clearly lacks foundation to opine regarding these subjects. He has never worked at Illumina. (Freidin (Grail) Tr. 2965). With respect to Illumina's ability to accelerate Galleri's

FDA approval, [redacted]

Moreover, with respect to Grail, Mr. Freidin is not involved in any areas relating to whether there would be any "benefits of the Transaction" and does not have foundation to support such a "fact." Mr. Freidin is not in charge of Grail's product development team, competitive intelligence team, regulatory team, medical affairs team, quality team, market access team, clinical studies team, lab operations team, government affairs team, or Grail's communication with payers. (Freidin (Grail) Tr. 3136-37). Mr. Freidin testified at trial that Grail's FP&A team, which Mr. Freidin leads, did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145). Mr. Frieden testified at trial that Grail's Medical Affairs and Regulatory teams did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145). Mr. Freidin's opinions regarding whether there would be any "benefits of the Transaction," lack foundation, are unreliable, and should be disregarded by this Court.

[redacted] It is therefore unclear how, if at all, Mr. Freidin could determine that, from a capital-raising perspective, the Transaction would be preferable to the capital markets. [redacted] The evidence clearly demonstrates that Mr. Freidin lacks any foundation to discuss the "benefits of the Transaction."

Lastly, the proposed finding is misleading insofar as it implies the Transaction will result in "benefits," including with regard to FDA and "market access" acceleration. Such an implication is against the weight of the evidence, which demonstrates Illumina did not, in the ordinary course, anticipate accelerating Grail's regulatory approval or payer adoption and that [redacted] The evidence shows that the relevance of any experience Illumina has achieving reimbursement is questionable at best. Therefore, this Court should disregard the proposed finding.

1652. Mr. Freidin also testified that there was no guarantee that an IPO would have been successful; that, if a company doesn't execute and deliver after going public, their valuation

decreases and shares are diluted, which makes it more difficult to raise funds going forward; that investors raised concerns regarding broad adoption and FDA approval, which would have hampered investment; that investors raised concerns that GRAIL had already raised a lot of money for a company without revenues; and that, based on meetings with investors, it appeared that an IPO was not certain. (Freidin (GRAIL) Tr. 3024–26.)

Response to Finding No. 1652

The proposed finding is confusing because Respondents have improperly merged numerous proposed findings of fact together as a single composite "finding." Complaint Counsel objects to the composite nature of the proposed "finding" as improper. Respondents' combination of numerous largely unrelated statements is confusing and misleading to the extent Respondents intend to state one fact.

The proposed finding is vague. Respondents fail to define the terms "successful," "execute and deliver," "decreases," "more difficult," "concerns," "broad adoption," "hampered investment," "a lot of money," and "not certain."

The proposed finding is misleading, insofar as it implies that an IPO for Grail certainly would not have been successful. Such an implication is against the weight of the evidence, which demonstrates that Grail was well positioned for an IPO. In fact, [redacted]

[redacted]

The proposed finding is further misleading, insofar is it implies that there was "no guarantee that an IPO would have been successful" but there is a "guarantee" that the Transaction will be "successful." Such an implication is misleading. [redacted]

Lastly, rather than referencing evidence or testimony to substantiate this proposed finding (e.g., demonstrating the "concerns" from these "investors"), Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded. Therefore, this Court should disregard the proposed finding.

1653. [redacted]

Response to Finding No. 1653

[redacted]

[redacted]

1654. Mr. Freidin testified that GRAIL considered hiring outside consultants to achieve the above benefits; that consultants in general can provide high-level strategic roadmaps, but they don't stick around to watch the company grow and scale; that GRAIL needed help in operations and expertise in how to execute; that, in Mr. Freidin's experience, employees provide higher-quality product than consultants; that consultants can be more expensive overall because they do not stick around; and that consultants are not full-time, loyal employees. (Freidin (GRAIL) Tr. 3032–36.)

Response to Finding No. 1654

The proposed finding is confusing because Respondents have improperly merged numerous proposed findings of fact together as a single composite "finding." Complaint Counsel objects to the composite nature of the proposed "finding" as improper. Respondents' combination of numerous largely unrelated statements is confusing and misleading to the extent Respondents intend to state one fact.

The proposed finding is unreliable for two reasons. First, rather than referencing evidence or testimony to substantiate the very specific claims, Respondents cite only to the unfounded, self-serving testimony of a single Grail executive, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for the executive's base conjecture, this proposed finding of fact should be disregarded.

Second, the proposed finding is unreliable because Mr. Freidin lacks foundation to testify about this subject. Mr. Freidin is not in charge of Grail's product development team, competitive intelligence team, regulatory team, medical affairs team, quality team, market access team, clinical studies team, lab operations team, government affairs team, or Grail's communication

with payers. (Freidin (Grail) Tr. 3136-37). He has no foundation regarding whether Grail "needed help in operations [or] expertise in how to execute." In particular, he has no basis to determine whether, in general, "employees provide higher-quality product than consultants."

The proposed finding is vague. The terms "the above benefits," "in general," "expertise in how to execute," "higher-quality product," "more expensive overall," and "loyal" are undefined and ambiguous.

[redacted]

Therefore, this Court should disregard the proposed finding.

1655. [redacted]

Response to Finding No. 1655

[redacted]

[redacted]

1656. [redacted]

Response to Finding No. 1656

[redacted]

[redacted]

1657. Mr. Freidin testified that the lawsuit by Complaint Counsel caused all integration to cease. (Freidin (GRAIL) Tr. 3168.)

Response to Finding No. 1657

The proposed finding is misleading to the extent it suggests that the lawsuit itself somehow specifically prohibited Respondents from engaging in integration planning efforts. The parties are not subject to a preliminary injunction in the United States. Moreover, Respondents cite no order of this Court that prevents them from engaging in premerger integration planning. In the United States, the level of coordination permitted during the premerger process is governed by the federal antitrust laws. The parties are prohibited by the

federal antitrust laws from engaging in collective actions that adversely affect competition. (*See, e.g.*, 15 U.S.C. § 1 (prohibiting agreements that unreasonably restrain trade); 15 U.S.C. § 45 (prohibiting unfair methods of competition); 15 U.S.C. § 2 (prohibiting monopolization, attempts to monopolize, and conspiracies to monopolize). To the extent that Respondents have made the independent determination that any form of premerger integration planning would adversely affect competition and violate the antitrust laws, that is their own determination and not the result of any specific prohibition related to the instant administrative proceeding.

Additionally, Respondents chose to close the Acquisition in August 2021 despite a standstill order from the European Commission; when they did so, they promised to hold Grail separate from Illumina, meaning that Grail "will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis." (deSouza (Illumina) Tr. 2463; [redacted]

1658. Mr. Freidin testified that GRAIL did not believe it was necessary to formally model the acceleration benefits of the acquisition because "they were just obvious to us. You know, a royalty goes away, access increases, price can come down. You know, Illumina is a multinational, billion dollar, multiproduct company. They have got international operations.

They have got commercial experience. Also, they have got FDA success, again, things that GRAIL does not have. So it was just obvious." (Freidin (GRAIL) Tr. 3167–68.) Further, when asked if he had modeled any dissynergies, he responded, "No. I can't think of any or couldn't think of any." (Freidin (GRAIL) Tr. 3168.)

Response to Finding No. 1658

Complaint Counsel does not disagree that Grail did not model acceleration efficiencies. Complaint Counsel also does not disagree that Mr. Freidin's basis for his various claims related to the purported acceleration benefits of the deal can be adequately summarized by Mr. Freidin's statement that "they were just obvious to us." [redacted] Therefore, this Court should disregard the proposed finding.

4. **Arash Jamshidi**

a. Background

1659. Dr. Arash Jamshidi is the Senior Vice President of Data Sciences at GRAIL. He began his role near the end of 2020. Jamshidi also joined the executive leadership team about a year and a half ago. (Jamshidi (GRAIL) Tr. 4013–4014.)

Response to Finding No. 1659

The proposed finding is vague because the terms "his role," "near the end of" and "about" are imprecise and undefined. The proposed finding is also vague because the phrase

"about a year and a half ago" is itself vague and not tethered to any specific date, and so it is unclear if Respondents mean not suggests that Dr. Jamshidi joined the executive leadership team about a year and a half prior to trial or a year and a half prior to the date on which the proposed findings were filed. Therefore, this Court should disregard the proposed finding.

1660. As Senior Vice President of Data Science, Dr. Jamshidi manages a team of about 90 individuals, that analyze GRAIL's data developed through clinical studies and develop machine-learning and classification algorithms from the data. His primary responsibility is managing groups around bioinformatics, data sciences, clinical data management and biostatistics. (Jamshidi (GRAIL) Tr. 4017.)

Response to Finding No. 1660

Complaint Counsel does not disagree that Dr. Jamshidi is Senior Vice President of Data Science at Grail or that he testified generally as described in this finding. For clarity, however, Complaint Counsel notes that Dr. Jamshidi did not testify that the team he oversees develops machine-learning and classification algorithms "from" data, but rather that it develops machine-learning and classification algorithms "using" data. Additionally, while Dr. Jamshidi described his duties as Senior Vice President of Data Science, he did not characterize any particular task or tasks as his "primary responsibility." Therefore, this Court should disregard the proposed finding.

1661. Dr. Jamshidi has a master's and Ph.D. from UC Berkeley, where he also completed some post-doctoral work between 2005 and 2011. He completed his undergraduate studies at Simon Fraser University in Canada and did some university work at Sharif University in Iran. (Jamshidi (GRAIL) Tr. 4014.)

Response to Finding No. 1661

Complaint Counsel has no specific response to the proposed finding.

1662. Prior to joining GRAIL, Dr. Jamshidi spent about five years at Illumina in multiple positions, including Senior Staff Scientist, Staff Scientist and different scientific roles. His most recent position at Illumina was Associate Director of Research. (Jamshidi (GRAIL) Tr. 4015.)

Response to Finding No. 1662

Complaint Counsel has no specific response to the proposed finding.

1663. Before becoming Senior Vice President of Data Sciences, Dr. Jamshidi was the President of Bioinformatics and Data Sciences at GRAIL and was part of the founding group of GRAIL. (Jamshidi (GRAIL) Tr. 4015–4016.)

Response to Finding No. 1663

Complaint Counsel has no specific response to the proposed finding.

b. Testimony

1664. The Galleri Test. Dr. Jamshidi testified that Galleri is a multicancer early detection test which aims to be able to detect cancer early in an asymptomatic population that's generally at elevated risk, with a focus on adults ages 50 and above; and that the key performance attributes for Galleri include sensitivity, specificity, accuracy of calling the cancer signal origin, and positive predictive value. (Jamshidi (GRAIL) Tr. 4021–22.)

Response to Finding No. 1664

Complaint Counsel has no specific response to the proposed finding.

1665. [redacted]

Response to Finding No. 1665

[redacted]

[redacted]

1666. [redacted]

Response to Finding No. 1666

[redacted]

[redacted]

1667. [redacted]

Response to Finding No. 1667

[redacted]

[redacted]

1668. Efficiencies. [redacted]

Response to Finding No. 1668

[redacted]

[redacted]

1669. [redacted]

Response to Finding No. 1669

[redacted]

[redacted]

5. **Christopher Della Porta**

a. Background

1670. Christopher Della Porta is Director of Growth Strategy at GRAIL. (Della Porta (GRAIL) Tr. 453–454.) The Growth Strategy group was founded by Della Porta and functions primarily to develop new channels for the sale of Galleri by evaluating and approaching potential customers. (Della Porta (GRAIL) Tr. 455.) Della Porta has served as Director of Growth Strategy since September of 2020. (Della Porta (GRAIL) Tr. 454.)

Response to Finding No. 1670

Complaint Counsel has no specific response.

1671. Prior to September of 2020, Della Porta served as Associate Director of Product Marketing, Senior Manager of Product Marketing and Product Marketing Manager. (Della Porta (GRAIL) Tr. 454.)

Response to Finding No. 1671

Complaint Counsel has no specific response.

b. Testimony

1672. [redacted]

Response to Finding No. 1672

[redacted]

[redacted]

[redacted]

1673. GRAIL's Alleged Competitors. [redacted]

Response to Finding No. 1673

[redacted]

[redacted]

[redacted]

1674. [redacted]

Response to Finding No. 1674

[redacted]

[redacted]

[redacted]

[redacted]

1675. [redacted]

Response to Finding No. 1675

[redacted]

1676. [redacted]

Response to Finding No. 1676

[redacted]

1677. *Exact/Thrive*. [redacted]

[redacted]

Response to Finding No. 1677

[redacted]

[redacted]

[redacted]

1678. *Natera*. [redacted]

Response to Finding No. 1678

[redacted]

[redacted]

[redacted]

[redacted]

1679. *Guardant*. [redacted]

Response to Finding No. 1679

[redacted]

[redacted]

[redacted]

1680. *Freenome*. [redacted]

Response to Finding No. 1680

[redacted]

[redacted]

[redacted]

1681. *Singlera*. [redacted]

Response to Finding No. 1681

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1682. *FMI.* [redacted]

Response to Finding No. 1682

[redacted]

[redacted]

[redacted]

1683. *Helio Health*. [redacted]

Response to Finding No. 1683

[redacted]

[redacted]

[redacted]

1684. Efficiencies. Mr. Della Porta testified that Illumina's acquisition of GRAIL will result in the acceleration of Galleri.

Response to Finding No. 1684

The proposed finding is unreliable, misleading, wholly unsupported and against the weight of substantial evidence demonstrating that Illumina's claimed efficiencies are not verifiable, not merger-specific, and not likely to be passed on to consumers. *See* Responses to RPFF ¶¶ 1685-1688. The proposed finding is merely a conclusory statement with no citation to the record and should be disregarded on that basis alone.

As explained in the responses of the next several proposed findings, Mr. Della Porta's testimony lacks foundation to make any claims related to Illumina's alleged efficiencies, as he does not have the requisite knowledge or expertise to testify that the transaction will result in such claimed efficiencies. Mr. Della Porta testified that he has never worked for Illumina (Della Porta (Grail) Tr. 580), has not performed any calculations, analyses or core tasks of the expected acceleration of the commercialization of Galleri as a result of the acquisition by Illumina (Della Porta (Grail) Tr. 580), has no responsibilities at Grail with respect to obtaining regulatory approval (Della Porta (Grail) Tr. 582), is not a scientist, regulatory specialist, engineer, doctor, and does not draft Grail's submissions to the FDA nor plan Grail's clinical trials (Della Porta (Grail) Tr. 582-83). Further, Mr. Della Porta did not monitor competitors' clinical trials nor did

he track competitors' research and development efforts. (Della Porta (Grail) Tr. 583). Therefore, this Court should disregard the proposed finding.

1685. *Acceleration of Galleri.* Mr. Della Porta testified that Galleri has been having challenges making sales; Illumina's previous experience launching products in NIPT and its additional resourcing across functions, including regulatory, market access and sales, would accelerate the adoption of Galleri; and Illumina could help increase Galleri's sales in the health system, employer and physician channels through its relationships, footprint, reputation and resources. [redacted]

Response to Finding No. 1685

[redacted]

[redacted]

[redacted]

1686. Mr. Della Porta testified that simply hiring employees from Illumina would not be sufficient to accelerate adoption by health systems and employers because the name, brand and

scale of Illumina, combined with its significant talent pool, cannot be easily hired. (Della Porta (GRAIL) Tr. 588.)

Response to Finding No. 1686

[redacted]

[redacted]

[redacted]

1687. *Acceleration of DAC.* [redacted]

Response to Finding No. 1687

[redacted]

[redacted]

1688. *Acceleration of International Expansion.* [redacted]

Response to Finding No. 1688

[redacted]

[redacted]

[redacted]

C. Third Parties

1. Kevin Conroy (Exact)

a. Background

1689. Kevin Conroy is the Chairman and CEO of Exact Sciences. (Conroy (Exact/Thrive) Tr. 1526.)

Response to Finding No. 1689

Complaint Counsel has no specific response to this proposed finding.

1690. As Chairman, Mr. Conroy is responsible for setting the agenda for the board of directors. (Conroy (Exact/Thrive) Tr. 1527.)

Response to Finding No. 1690

Complaint Counsel has no specific response to this proposed finding.

1691. As CEO, he is responsible for the general operations of the company including the merger and acquisition strategy, strategic planning and commercialization planning. (Conroy (Exact/Thrive) Tr. 1527–29.)

Response to Finding No. 1691

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1692. Alleged relevant market. [redacted] the company may need to

explore a number of different biomarker combinations and alternative candidate products and platform technologies accordingly, or repeat clinical studies before identifying a potentially successful candidate (Conroy (Exact/Thrive) Tr. 1717).

Response to Finding No. 1692

[redacted]

[redacted]

1693. [redacted]

Response to Finding No. 1693

[redacted]

[redacted]

1694. Mr. Conroy admitted that CancerSEEK is subject to considerable risk, as the long-term success of the various early cancer screening tests in development is going to depend significantly on a whole host of scientific and regulatory variables. (Conroy (Exact/Thrive) Tr. 1709, 1711.)

Response to Finding No. 1694

[redacted]

[redacted]

1695. Mr. Conroy admitted that candidate products that may initially show promise may fail to achieve the desired results in large clinical trials, they may not achieve acceptable levels of accuracy, and results from early studies or trials are not necessarily predictive of future clinical trial results. (Conroy (Exact/Thrive) Tr. 1712.) He admitted that if in a clinical study a

candidate product fails to identify even a small number of cancer cases, the sensitivity rate may be materially and adversely affected. (Conroy (Exact/Thrive) Tr. 1716–17.)

Response to Finding No. 1695

[redacted]

[redacted]

1696. [redacted]

Response to Finding No. 1696

[redacted]

[redacted]

1697. [redacted]; and healthcare providers may be reluctant to prescribe and patients may be reluctant to complete Exact's tests if they're not confident that patients will be reimbursed for those tests (Conroy (Exact/Thrive) Tr. 1719).

Response to Finding No. 1697

[redacted]

[redacted]

[redacted]

[redacted]

1698. Mr. Conroy admitted that product development is expensive and may take years to complete and can have uncertain outcomes, and failure can occur at any stage of development (Conroy (Exact/Thrive) Tr. 1717–18): if, after development, a candidate product appears successful, Exact may need to obtain FDA and other regulatory clearances or approvals before it can market the product, which are likely to involve significant time as well as additional research and development and clinical study expenditures (Conroy (Exact/Thrive) Tr. 1718); there can be no guarantee that the FDA would clear or approve any future product or service that Exact/Thrive may develop (Conroy (Exact/Thrive) Tr. 1718); and the commercial success of a product is going to depend upon a variety of factors, like acceptance in the medical community, patient acceptance and demand, and coverage and reimbursement by third-party payers (Conroy (Exact/Thrive) Tr. 1718–19).

Response to Finding No. 1698

[redacted]

[redacted]

[redacted]

[redacted]

1699. Mr. Conroy admitted that Exact/Thrive's CancerSEEK is not a substitute for, but is highly differentiated from, GRAIL's Galleri test, as the Galleri test is the only multicancer screening test based on DNA on the market (Conroy (Exact/Thrive) Tr. 1709); Exact/Thrive does not have evidence that CancerSEEK's detection technology will ultimately be able to detect the same amount of cancers as GRAIL's test (Conroy (Exact/Thrive) Tr. 1651); the Cohen study for the CancerSEEK test only focused on eight cancer types (Conroy (Exact/Thrive) Tr. 1699); and in the DETECT-A study, the CancerSEEK blood test identified only ten cancer types and failed to detect six cancers (Conroy (Exact/Thrive) Tr. 1706–07).

Response to Finding No. 1699

[redacted]

[redacted]

[redacted]

1700. [redacted]; and that the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08).

Response to Finding No. 1700

[redacted]

[redacted]

[redacted]

[redacted]

1701. Mr. Conroy admitted that each one of the cancer screening tests in development could be different from one another based on types of cancer they detect, the technologies they use, their sensitivities and specificities, their different uses and their payer coverage. (Conroy (Exact/Thrive) Tr. 1709–10.)

Response to Finding No. 1701

[redacted]

[redacted]

1702. Mr. Conroy could not say with any certainty which of the tests in development will actually come to market and be commercially successful. (Conroy (Exact/Thrive) Tr. 1710.)

Response to Finding No. 1702

[redacted]

[redacted]

1703. Alleged foreclosure. [redacted]

Response to Finding No. 1703

[redacted]

1704. [redacted]

[redacted]

Response to Finding No. 1704

[redacted]

1705. [redacted]

[redacted]

Response to Finding No. 1705

[redacted]

1706. [redacted]

Response to Finding No. 1706

[redacted]

[redacted]

1707. [redacted]

Response to Finding No. 1707

[redacted]

1708. [redacted]
}
Exact/Thrive does not have any rights to the GRAIL IP or an IP license of any kind from GRAIL and has never had any expectation that it would be given access to GRAIL's IP as a mechanism to develop the CancerSEEK test (Conroy (Exact/Thrive) Tr. 1730); Exact/Thrive does not have any confidential information about Illumina's proprietary products or reagents (Conroy (Exact/Thrive) Tr. 1730); and Exact/Thrive does not currently share any pricing plans with, has never tried to purchase data from Illumina, and has no plans to purchase any data from Illumina in the future (Conroy (Exact/Thrive) Tr. 1733–34).

Response to Finding No. 1708

[redacted]

1709. Open Offer. [redacted] has not read Illumina's full open offer, and does not know the details of the open offer (Conroy (Exact/Thrive) Tr. 1725–26).

Response to Finding No. 1709

[redacted]

[redacted]

1710. Mr. Conroy admitted that when the Illumina/GRAIL transaction was announced, it was Exact's expectation that Exact could reach a long-term supply agreement that would be in the mutual best interests of both Illumina and Exact. (Conroy (Exact/Thrive) Tr. 1723–24.)

Response to Finding No. 1710

[redacted]

1711. Mr. Conroy admitted that through the Open Offer, Illumina has committed to lower the volume-based net price per gigabase of sequencing 43 percent by 2025. (Conroy (Exact/Thrive) Tr. 1732.)

Response to Finding No. 1711

[redacted]

[redacted]

1712. Mr. Conroy admitted that Exact relies on contracts to run its business, despite the fact that no contract is perfect and no contract can address all potential issues that might eventualize over a long term. (Conroy (Exact/Thrive) Tr. 1723.)

Response to Finding No. 1712

[redacted]

1713. Efficiencies. [redacted] but Mr. Conroy admitted that the widespread adoption of an MCED test will save lives and that the acceleration of any cancer screening test will save lives (Conroy (Exact/Thrive) Tr. 1737, 1739-40.)

Response to Finding No. 1713

The proposed finding is misleading and does not provide the full context of Mr. Conroy's testimony. [redacted] The proposed finding is also misleading. Mr. Conroy makes clear that the acceleration of any test to market can save lives. (Conroy (Exact) Tr. 1739). Mr. Conroy, however, was very careful to explain that "[a]s a CEO of a company that is

regulated by the FDA one thing we don't do is talk about saving lives as it relates to a specific test, and there are reasons for that." (Conroy (Exact) Tr. 1739). Therefore, this Court should disregard the proposed finding.

1714. Mr. Conroy admitted that developing your cancer screening test requires a Herculean effort: from a practical perspective, getting paid under Medicare without FDA approval would be impossible, getting paid by commercial payers without FDA approval would be improbable and it would be very challenging for an MCED test to become viable long-term if it were ineligible for Medicare reimbursement, which is going to depend on a lot of factors, including the sufficiency of the sensitivity and specificity of the test and on whether the test is reliable, safe, effective, and medically necessary. (Conroy (Exact/Thrive) Tr. 1734–35.)

Response to Finding No. 1714

[redacted]

[redacted]

[redacted]

1715. [redacted]

Response to Finding No. 1715

[redacted]

1716. Bias. [redacted]

[redacted]

Response to Finding No. 1716

[redacted]

1717. [redacted]

Response to Finding No. 1717

[redacted]

1718. [redacted]

[redacted]

Response to Finding No. 1718

[redacted]

2. **Christopher Lengauer (Exact/Thrive/Third Rock)**

a. Background

1719. Dr. Lengauer was a cofounder and Chief Innovation Officer of Thrive, and is currently a consultant to Exact Sciences, overseeing strategy at Thrive and a part of Thrive's management leadership team involved in the progression of the CancerSEEK test. (Lengauer (Exact/Thrive) Tr. 156–57.)

Response to Finding No. 1719

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1720. Alleged Relevant Market. [redacted]

Response to Finding No. 1720

[redacted]

[redacted]

[redacted]

1721. [redacted]

[redacted]

Response to Finding No. 1721

[redacted]

[redacted]

1722. [redacted]

Response to Finding No. 1722

[redacted]

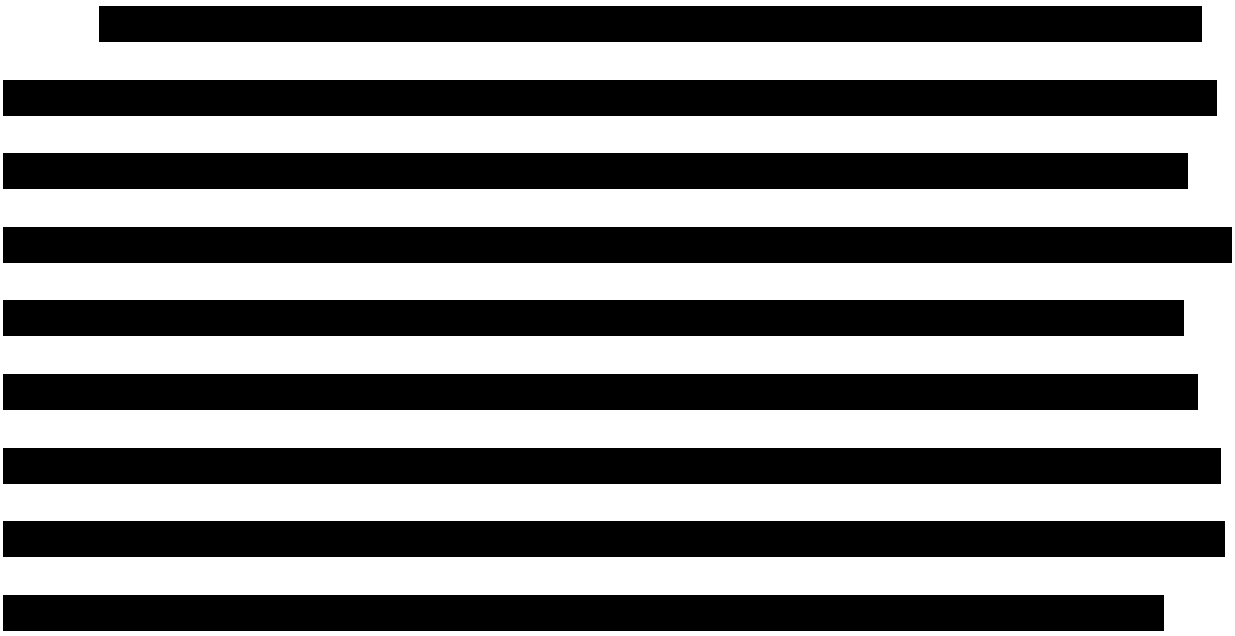
1723. Dr. Lengauer admitted that the DETECT-A prospective, interventional trial showed critical flaws with CancerSEEK test: CancerSEEK Alpha protocol as it was studied in the DETECT-A trial included two blood tests and also a PET-CT scan; the first step of the DETECT-A protocol was a baseline blood test that analyzed variant and protein biomarkers; the second step was a confirmation blood test to rule out an abnormal biomarker reading due to CHIP; only if both the baseline and the confirmatory blood tests were positive, then the overall blood test was considered positive; the participants with two positive blood tests were then

reviewed by a multidisciplinary review committee which recommended whether a full body PET-CT scan would be performed in order to detect the origin of the cancer; and the diagnostic PET-CT scan was required to confirm the results of the blood testing and to localize the potential cancer. (Lengauer (Exact/Thrive) Tr. 246–48, 260.)

Response to Finding No. 1723

The proposed finding is unsupported, incomplete and misleading. First, the proposed finding is misleading because it claims Dr. Lengauer admitted there were "critical flaws" with the CancerSEEK test, but in fact, Dr. Lengauer never described any aspect of the DETECT-A study using either the word "critical" or "flaw." Therefore, the proposed finding is entirely lacking in support, misstates Dr. Lengauer's testimony, and should be disregarded.

Second, this Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46.



[redacted]

Fourth, the proposed finding is misleading to the extent it implies that Thrive's use of a PET-CT scan is unhealthy, harmful, or otherwise a disadvantage compared to other MCED tests such as Galleri. Dr. Lengauer testified that [redacted]

Finally, the proposed finding is misleading to the extent it implies that the "need to do additional biopsies to further characterize the cancer" is unhealthy, harmful, or otherwise a disadvantage compared to other MCED tests such as Galleri. [redacted] Therefore, the proposed finding should be disregarded.

1724. Dr. Lengauer admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and

follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol (Lengauer (Exact/Thrive) Tr. 248–50); investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer (Lengauer (Exact/Thrive) Tr. 249-50).

Response to Finding No. 1724

The proposed finding is unsupported, incomplete, and misleading. The proposed finding is unsupported because it is based on hearsay—rather than cite to testimony from the actual investigators of the DETECT-A trial for what they may have "recognized" (or at least their study), Respondents instead cite to questions asked to Dr. Lengauer about what the investigators recognized. *See* (Lengauer (Thrive) Tr. 249-250).

Second, the proposed finding is incomplete and misleading to the extent it implies that Thrive's use of a PET-CT scan is unhealthy, harmful, or otherwise a disadvantage compared to other MCED tests such as Galleri. Dr. Lengauer testified that [redacted]

Third, the proposed finding is misleading to the extent it implies that the "need to do additional biopsies to further characterize the cancer" is unhealthy, harmful, or otherwise a disadvantage compared to other MCED tests such as Galleri. [redacted]

Finally, the proposed finding is also misleading to the extent it suggests that Galleri is a "liquid biopsy-only test" in a way that CancerSEEK is not. Galleri's cancer signal of origin ("CSO") algorithm cannot reliably identify the location of cancer without the need for additional

diagnostic testing including, in many cases, PET-CT. [redacted] Grail's CEO, Hans Bishop, testified at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387). The authors of Grail's CCGA-3 substudy also acknowledge that individuals who receive a positive Galleri result "may require a whole-body computed tomography (CT) or positron emission tomography (PET)-CT scan to localize the primary tumor." (RX3409 at 009 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021)). [redacted]

Grail undertook the PATHFINDER study to assess the extent and types of diagnostic testing that will be required to achieve diagnostic resolution following a positive Galleri result and cancer signal of origin ("CSO") predication. (*See* RPFF ¶ 395 ("PATHFINDER's primary goal is to assess the extent and types of diagnostic testing required to achieve a diagnostic resolution after a patient has received a cancer screening test result that indicates 'Signal Detected', meaning the potential presence of cancer, along with a predicted or indeterminate tissue of origin.")). If Grail had already established the extent to which PET-CT and other types of diagnostic testing would be required to achieve diagnostic resolution when Galleri is used in a real-world setting, such a study would not be necessary. Interim results from PATHFINDER indicate that additional imaging testing was overwhelmingly required to achieve diagnostic

resolution for patients who received positive Galleri results. According to the preliminary results of PATHFINDER, "[m]ost participants with diagnostic resolution had at least 1 imaging test (57/63; 90%)." RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021) (the presentation fails to disclose the share of imaging tests that were PET-CT tests). Over half of positive results in PATHFINDER were false positives; 25 percent of participants who received falsely positive Galleri results wound up undergoing at least one invasive procedure. RX3041 at 003 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)). Therefore, the proposed finding should be disregarded.

1725. Dr. Lengauer admitted that in the DETECT-A trial, CancerSEEK showed the ability to detect cancers only in ten primary organs: appendix, breast, colorectal, kidney, lung, lymphoma, ovary, thyroid, and uterine cancers, and carcinoma of unknown primary. (Lengauer (Exact/Thrive) Tr. 243, 260–61.)

Response to Finding No. 1725

The proposed finding is also misleading to the extent that its characterization of DETECT-A as "only" detecting cancers of 10 organs is meant to suggest that CancerSEEK is capable of detecting fewer early cancers in a screening setting than Grail. In fact, the opposite is the case. Galleri has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (RX3041 at 005 (Tomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021) (showing seven cancers as being detected in Stages I-III: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine); *see also* Cote Tr. 4000-01).

[redacted]

[redacted]

1726. Dr. Lengauer also admitted that the CancerSEEK blood test has a high false-positive rate: of the about 9,900 participants actually were tested with the baseline blood test in the DETECT-A trial, 490 participants had a positive baseline test; of the 490 participants who had a positive baseline test in the DETECT-A trial, only 134 participants had two positive blood tests and no CHIP; of the 134 participants who had two positive blood tests and no CHIP, 116 had a full-body PET-CT scan and 11 of them had other imaging; of the 127 participants who had

imaging, 15 participants who had the PET-CT scan were found to have cancer and all of the 11 by other imaging have cancer; of the 490 participants who had a positive baseline test in the DETECT-A trial, only 26 cancers were actually detected. (Lengauer (Exact/Thrive) Tr. 251–53, 256.)

Response to Finding No. 1726

The proposed finding is vague, misleading and incorrect because it uses statistics from the DETECT-A study to purportedly describe CancerSEEK despite the fact that Dr. Lengauer testified that since the DETECT-A study, Thrive has continued to improve CancerSEEK. (CCFF ¶ 2058). Thus, the proposed finding is improper and unsupported because it cites Dr. Lengauer's testimony about the version of CancerSEEK used in the Detect-A study and implies that these findings reflect the *current, improved* version of CancerSEEK.

[redacted]

[redacted]

1727. [redacted] 257–59; 262.)

Response to Finding No. 1727

[redacted]

[redacted]

[redacted]

1728. [redacted]

Response to Finding No. 1728

[redacted]

[redacted]

1729. [redacted]

Response to Finding No. 1729

[redacted]

[redacted]

1730. [redacted]

Response to Finding No. 1730

[redacted]

1730.1 [redacted], 244–45, 262–63.)

Response to Finding No. 1730.1

[redacted]

[redacted]

1731. [redacted]

Response to Finding No. 1731

[redacted]

1732. [redacted]

Response to Finding No. 1732

[redacted]

1733. [redacted]

Response to Finding No. 1733

[redacted]

[redacted]

1734. Alleged Foreclosure. [redacted]

Response to Finding No. 1734

[redacted]

[redacted]

1734.1 [redacted]

Response to Finding No. 1734.1

[redacted]

[redacted]

[redacted]

1734.2 [redacted]

Response to Finding No. 1734.2

[redacted]

[redacted]

1734.3 [redacted]

Response to Finding No. 1734.3

[redacted]

[redacted]

[redacted]

1735. [redacted]

Response to Finding No. 1735

[redacted]

[redacted]

[redacted]

1736. [redacted]

Response to Finding No. 1736

[redacted]

1737. [redacted]

[redacted]

Response to Finding No. 1737

[redacted]

1738. [redacted]

Response to Finding No. 1738

[redacted]

1739. [redacted]

[redacted]

Response to Finding No. 1739

[redacted]

1740. [redacted]

[redacted]

Response to Finding No. 1740

[redacted]

[redacted]

[redacted]

1741. [redacted]

Response to Finding No. 1741

[redacted]

[redacted]

1742. [redacted]

Response to Finding No. 1742

[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]

[redacted]

1743. [redacted]

Response to Finding No. 1743

[redacted]

[redacted]

1744. Bias. Complaint Counsel presented Dr. Lengauer as an unbiased witness, but Dr. Lengauer admitted that he met with the FTC four times without any representatives of Illumina or GRAIL before providing his testimony. (Lengauer (Exact/Thrive) Tr. 263–64.)

Response to Finding No. 1744

The proposed finding is unsupported, incorrect, and misleading to the extent it is meant to suggest that Dr. Lengauer's testimony is not accurate or credible. Respondents do not cite to any testimony (or other evidence) regarding the substance of Dr. Lengauer's discussions with the

FTC, whether the discussions related to the substance of any topics of Dr. Lengauer's trial testimony (rather than, for instance, procedural matters related to the deposition and trial testimony), or that the discussions in any way impacted any substance of any of Dr. Lengauer's testimony. Moreover, Dr. Lengauer's testimony is corroborated both by the testimony of other MCED witnesses as well as by Respondents' ordinary course documents. *See, e.g.*, (CCFF ¶¶ 3231-3284). Finally, Dr. Lengauer testimony regarding Exact/Thrive's efforts to research, develop, and commercialize an MCED test is based on extensive, personal knowledge, including, but not limited to, the following:

- Dr. Christoph Lengauer is a co-founder of Thrive Earlier Detection, which is now owned by Exact Sciences. Dr. Lengauer is currently a partner at Third Rock Ventures, a venture fund that invests mainly in companies that the fund creates and builds themselves. (CCFF ¶ 5967).
- Dr. Lengauer serves as a consultant to Exact Sciences and, in this role, oversees Thrive's strategy. As part of his responsibilities, he serves on Thrive's management leadership team and is involved in the development of the CancerSEEK test. (CCFF ¶ 5968).
- Prior to the Thrive's acquisition by Exact Sciences, Dr. Lengauer was the Chief Innovation Officer of Thrive since the company was founded, overseeing the development of Thrive's CancerSEEK blood-based test and was involved in decision-making and regulatory strategy. (CCFF ¶ 5969).
- Before serving as a partner of Third Rock Ventures, Dr. Lengauer was the Chief Scientific Officer at Blueprint Medicines, which is a biotech company focused on oncology drug discovery. Before that role, Dr. Lengauer was the Global Head of Oncology Research for Sanofi. (Lengauer (Third Rock Ventures) Tr. 158). Dr. Lengauer led the target identification and validation group of Novartis before transitioning to the role at Sanofi. (CCFF ¶ 5970).
- Dr. Lengauer has a Ph.D. in biology from the University of Heidelberg (Germany) and has a Master of Business Administration degree from Johns Hopkins University. In addition, Dr. Lengauer currently is an adjunct associate professor at Johns Hopkins University. (CCFF ¶ 5971).
- Dr. Lengauer completed postdoctoral training at Johns Hopkins University with the laboratory of Bert Vogelstein and Ken Kinzler. Following this training, Dr. Lengauer worked in this laboratory developing a greater understanding of the nature of genetics and cancer for approximately ten years. (CCFF ¶ 5972).

Therefore, the proposed finding should be disregarded.

3. Konstantin Fiedler (FMI)

a. Background

1745. Dr. Konstantin Fiedler is the Chief Operating Officer of Foundation Medicine (FMI), a wholly owned subsidiary of Roche that specializes in diagnostic testing. (Fiedler (FMI) Tr. 4463–66.)

Response to Finding No. 1745

Complaint Counsel has no specific response to this proposed finding.

1746. As Chief Operating Officer, Dr. Fiedler oversees all aspects of operation, from sample arrival at FMI facilities through results reporting. (Fiedler (FMI) Tr. 4464–65.) Dr. Fiedler reports to FMI's CEO. (Fiedler (FMI) Tr. 4465.)

Response to Finding No. 1746

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1747. Alleged relevant market. [redacted]

Response to Finding No. 1747

[redacted]

[redacted]

1748. Dr. Fiedler also testified that the only multicancer screening test on the market is Galleri and that he does not know how the cancer screening market may look or evolve in 12 years. (Fiedler (FMI) Tr. 4468–69.)

Response to Finding No. 1748

[redacted]

[redacted]

1749. Alleged foreclosure. Complaint Counsel contends the reunion of Illumina and GRAIL will change Illumina's incentives toward its customers, but Dr. Fiedler testified that FMI, which competes with Illumina's TSO500 product, has never had any concerns in its relationship with Illumina. (Fiedler (FMI) Tr. 4469–70.) Specifically, Dr. Fiedler testified that: FMI has been a customer of Illumina since FMI was started; FMI's first supply agreement with Illumina was signed in 2013; since 2019, FMI has purchased well over a hundred million, probably 140 million, in NGS products from Illumina; and during the time that FMI has been an Illumina customer FMI has had no issues or problems with Illumina servicing the Illumina instruments that FMI uses. (Fiedler (FMI) Tr. 4470.) Dr. Fiedler has never known Illumina to delay providing services or replacement parts to FMI; Illumina has acted in good faith with respect to its obligations under the 2013 supply agreement; Illumina has never "monkeyed with supply"; Illumina has never interrupted supply to FMI because it claimed FMI had infringed on Illumina's intellectual property; Illumina has never reneged on a commitment it made to FMI; FMI is a satisfied customer and FMI trusts Illumina to abide by its commitments. (Fiedler (FMI) Tr. 4471–72.)

Response to Finding No. 1749

[redacted]

[redacted]

1750. Complaint Counsel argues that one way Illumina may disadvantage other test developers is to raise the cost of sequencing but Dr. Fiedler testified that since 2018, the costs of sequencing have gone down due to upgrades on the platform that Illumina provided to FMI with higher throughput, and he assumes the cost of sequencing will also go down in the future. (Fiedler (FMI) Tr. 4469.)

Response to Finding No. 1750

[redacted]

[redacted]

1751. [redacted]

Response to Finding No. 1751

[redacted]

[redacted]

1752. The Transaction. [redacted]

Response to Finding No. 1752

[redacted]

1753. [redacted]

Response to Finding No. 1753

[redacted]

[redacted]

[redacted]

1754. Fiedler Declaration. [redacted]

Response to Finding No. 1754

[redacted]

1755. The declaration states, among other things, that: "On March 4, 2021, FMI entered into an amended and restated supply agreement with Illumina incorporating these commitments. This agreement contains the following terms: Access to similar overall commercial terms. including pricing, to purchase Illumina's NGS products as those offered to similarly situated customers, including GRAIL. Access to a 12–year supply agreement with Illumina, including assurances that there shall be no interruption in supply of NGS products because of any claim for IP infringement. Access to pre-release sequencing products from Illumina at substantially the same time as GRAIL and other for-profit sequencing companies have access. Establishment of a firewall to prevent GRAIL and any of its employees from accessing any confidential information

FMI is required, or elects, to share with Illumina after the acquisition of GRAIL. With these expanded protections under the amended and restated supply agreement, FMI believes it will continue to have access to the Illumina technology that is critical to FMI's tests over the term of the agreement. On that basis, FMI believes the concerns previously expressed to the FTC in connection with its investigation of Illumina's proposed acquisition of GRAIL have been adequately addressed."

Response to Finding No. 1755

[redacted]

[redacted]

1756. Open Offer / Amendment to the Illumina/FMI Supply Agreement. [redacted]

Response to Finding No. 1756

[redacted]

[redacted]

1757. [redacted]

Response to Finding No. 1757

[redacted]

[redacted]

[redacted]

1758. *Pricing Terms.* [redacted]

Response to Finding No. 1758

[redacted]

[redacted]

1759. [redacted]

Response to Finding No. 1759

[redacted]

[redacted]

[redacted]

1760. [redacted]

Response to Finding No. 1760

[redacted]

[redacted]

1761. Dr. Fiedler testified that he trusted Illumina that FMI would receive the same pricing as GRAIL under the supply agreement. (Fiedler (FMI) Tr. 4484.)

Response to Finding No. 1761

[redacted]

1762. *Supply Provisions.* [redacted]

[redacted]

Response to Finding No. 1762

[redacted]

[redacted]

1763. *Access to Pre-release Sequencing Products.* [redacted]

Response to Finding No. 1763

[redacted]

[redacted]

1764. [redacted]

Response to Finding No. 1764

[redacted]

[redacted]

1765. *Confidentiality/Firewall*. [redacted]

Response to Finding No. 1765

[redacted]

[redacted]

1766. [redacted]

Response to Finding No. 1766

[redacted]

1767. Efficiencies. Complaint Counsel contends the Transaction will not generate efficiencies, but Dr. Fiedler testified that it was beneficial to FMI to be acquired by Roche because it provided solid financial backing, allowed FMI to think more strategically and more long term, and FMI did not have to fulfill quarterly shareholder expectations. (Fiedler (FMI) Tr. 4472). Dr. Fiedler testified that he speculates that Illumina will help GRAIL makes its tests more widely available. (Fiedler (FMI) Tr. 4473.)

Response to Finding No. 1767

The proposed finding is confusing, misleading, incomplete, irrelevant, unreliable, and contrary to common sense. As an initial matter, Complaint Counsel does not disagree that Dr. Fiedler was "speculating" in his testimony. Dr. Fiedler testified that he does not "know what the details of the transaction between Illumina and Grail are," and thus when pressed by Respondents' counsel about whether Illumina will be able to help Grail make its tests more widely available, Dr. Fiedler responded, "I speculate yes." (Fiedler (FMI) Tr. 4473). This portion of Dr. Fiedler's testimony thus bears zero indicia of reliability.

The proposed finding is also confusing and irrelevant because it apparently attempts to link efficiencies that were purportedly achieved by the merger of Roche and FMI with Respondents' claimed efficiencies from the Illumina/Grail transaction with no explanation regarding why the two transactions are at all similar. Respondents appear to suggest that, because Dr. Fiedler personally considered it "beneficial to FMI to be acquired by Roche," the Illumina/Grail transaction will somehow generate cognizable, merger-specific efficiencies. But Respondents fail to explain why this conclusion follows logically, given that Dr. Fiedler was testifying about "benefits" rather than efficiencies in the antitrust sense, and given that Roche and FMI are very different companies than Illumina and Grail.

The proposed finding is also misleading to the extent that it suggests that the Illumina/Grail transaction will provide Grail with some of the same benefits that Dr. Fiedler ascribed to FMI after the Roche acquisition, including providing Grail with a "solid financial

backing" and allowing Grail to "think more strategically and more long term" by avoiding the need to "fulfill quarterly shareholder expectations." None of these benefits apply to the Illumina/Grail transaction. First of all, [redacted] Moreover, Grail was a privately held company prior to being acquired by Illumina, and thus it was not required to "fulfill quarterly shareholder obligations" and thus had free rein to "think more strategically and more long term" than a publicly traded company. Illumina, which is a publicly traded company, does have to "fulfill quarterly shareholder expectations," which may limit Grail's ability to "think more strategically and more long term." (PX0061 at 004 (Illumina 2020 Form 10-K)). Therefore, the comparison between the Roche/FMI transaction and the Illumina/Grail transaction fails on multiple levels.

This proposed finding, which is rooted in speculation and an inapt comparison between two completely dissimilar mergers, should be disregarded.

1768. Dr. Fiedler also testified that there are benefits to catching cancer early before it moves beyond stage one—where it is restricted to one organ—including that the patient can be treated very differently and the organ or parts of it can be removed; catching cancer early saves lives; multicancer screening tests can help catch cancer early; and the acceleration of a multicancer screening test on the market will save lives. (Fiedler (FMI) Tr. 4474.)

Response to Finding No. 1768

The proposed finding is misleading to the extent that it suggests that Illumina's acquisition of Grail will accelerate Galleri on the market. Dr. Fiedler has no foundation to testify regarding Respondents' claimed acceleration efficiencies.

4. **Michael Nolan (Freenome)**

a. Background

1769. Mr. Nolan is the CEO of Freenome. (Nolan (Freenome) Tr. 2695.) He has held this position since the end of April 2021. (Nolan (Freenome) Tr. 2695.) Prior to becoming

CEO, he served as the company's Chief Business Officer and Chief Commercial Officer. (Nolan (Freenome) Tr. 2695.)

Response to Finding No. 1769

Complaint Counsel does not disagree with the proposed finding.

b. Testimony

1770. Alleged Relevant Market. [redacted]

Response to Finding No. 1770

[redacted]

[redacted]

1771. [redacted]

Response to Finding No. 1771

[redacted]

[redacted]

[redacted]

1772. [redacted]

Response to Finding No. 1772

[redacted]

1773. [redacted]

Response to Finding No. 1773

[redacted]

[redacted]

[redacted]

[redacted]

1774. [redacted]

Response to Finding No. 1774

[redacted]

[redacted]

[redacted]

1775. [redacted]

Response to Finding No. 1775

[redacted]

[redacted]

1776. [redacted]

Response to Finding No. 1776

[redacted]

[redacted]

1777. [redacted]

Response to Finding No. 1777

1778.

Response to Finding No. 1778

[redacted]

1779. Alleged Foreclosure. [redacted]

Response to Finding No. 1779

[redacted]

[redacted]

1780. [redacted]

Response to Finding No. 1780

[redacted]

[redacted]

1781. [redacted]

Response to Finding No. 1781

[redacted]

[redacted]

[redacted]

1782. [redacted]

Response to Finding No. 1782

[redacted]

1783. [redacted]

Response to Finding No. 1783

[redacted]

[redacted]

1784. Open Offer. [redacted]

Response to Finding No. 1784

[redacted]

[redacted]

1785. [redacted]

Response to Finding No. 1785

[redacted]

[redacted]

1786. [redacted]

Response to Finding No. 1786

Complaint Counsel does not disagree with the proposed finding.

1787. [redacted]

[redacted]

Response to Finding No. 1787

[redacted]

[redacted]

[redacted]

1788. [redacted]

Response to Finding No. 1788

[redacted]

[redacted]

1789. [redacted]

Response to Finding No. 1789

[redacted]

[redacted]

1790. [redacted]

Response to Finding No. 1790

[redacted]

[redacted]

5. **Darya Chudova (Guardant)**

a. Background

1791. Dr. Chudova is a senior vice president of technology at Guardant Health. (Chudova (Guardant) Tr. 1135–36.)

Response to Finding No. 1791

Complaint Counsel has no specific response to this proposed finding.

1792. In this role Dr. Chudova oversees technology development projects that contribute to Guardant's clinical diagnostic assays, with a focus on screening applications. (Chudova (Guardant) Tr. 1137.)

Response to Finding No. 1792

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1793. Alleged Relevant Market. [redacted]

Response to Finding No. 1793

[redacted]

[redacted]

1794. [redacted]

Response to Finding No. 1794

[redacted]

[redacted]

1795. [redacted]

Response to Finding No. 1795

[redacted]

[redacted]

[redacted]

1796. [redacted]

Response to Finding No. 1796

[redacted]

[redacted]

1797. [redacted]

Response to Finding No. 1797

[redacted]

[redacted]

1798. [redacted]

Response to Finding No. 1798

[redacted]

[redacted]

1799. [redacted]

Response to Finding No. 1799

[redacted]

[redacted]

1800. [redacted]

[redacted]

Response to Finding No. 1800

[redacted]

[redacted]

1801. [redacted]

Response to Finding No. 1801

Complaint Counsel has no specific response to this request.

1802. [redacted]

Response to Finding No. 1802

[redacted]

[redacted]

1803. [redacted]

Response to Finding No. 1803

[redacted]

[redacted]

1804. [redacted]

Response to Finding No. 1804

[redacted]

[redacted]

1805. Alleged foreclosure. [redacted]

Response to Finding No. 1805

[redacted]

[redacted]

1806. [redacted]

Response to Finding No. 1806

[redacted]

[redacted]

1807. [redacted]

Response to Finding No. 1807

[redacted]

[redacted]

1807.1 [redacted]

Response to Finding No. 1807.1

[redacted]

[redacted]

1808. [redacted]

Response to Finding No. 1808

[redacted]

[redacted]

1809. [redacted]

Response to Finding No. 1809

[redacted]

[redacted]

1810. [redacted]

[redacted]

Response to Finding No. 1810

[redacted]

[redacted]

1811. [redacted]

Response to Finding No. 1811

[redacted]

[redacted]

1812. [redacted]

Response to Finding No. 1812

[redacted]

1813. Bias. [redacted]

Response to Finding No. 1813

[redacted]

6. **William Getty (Guardant)**

a. Background

1814. Mr. Getty is the Senior Vice President of Commercial for Guardant Health's Screening Division. (Getty (Guardant) Tr. 2482.)

Response to Finding No. 1814

Complaint Counsel has no specific response to this proposed finding.

1815. In this position, Mr. Getty's responsibilities include to lead the commercialization of Guardant's screening product in development, the LUNAR-2, which encompasses sales, marketing, medical affairs, commercial development and all manners of activities that will support its commercialization. (Getty (Guardant), Tr. 2483.)

Response to Finding No. 1815

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1816. Alleged relevant market. [redacted]

Response to Finding No. 1816

[redacted]

[redacted]

1817. [redacted]

Response to Finding No. 1817

[redacted]

[redacted]

[redacted]

1818. [redacted]

Response to Finding No. 1818

[redacted]

1819. [redacted]

Response to Finding No. 1819

[redacted]

[redacted]

1820. Mr. Getty admitted that Guardant's ability to achieve commercial success with its tests depends on a number of factors including the timing and scope of intended use of FDA approval, the timing and scope of coverage by all payers including commercial insurance payers and Medicare; Guardant has not achieved FDA approval for the LUNAR-2 test and the IDE or investigational device exemption Guardant received would not allow Guardant to go to market with a new medical diagnostic; and FDA approval for LUNAR-2 is not guaranteed: FDA review of PMA applications can be extensive, uncertain and lengthy; generally takes between one and three years but may take significantly longer; and many devices are not approved. (Getty (Guardant) Tr. 2646–50, 2661.)

Response to Finding No. 1820

[redacted]

[redacted]

1821. Mr. Getty admitted that Guardant does not have payer coverage either with Medicare or with private insurers for LUNAR-2 yet, even though Guardant's revenue depends on achieving broad insurance coverage, including private insurance as well as Medicare, for its tests; it is not guaranteed that insurance coverage will in fact be available for LUNAR-2; and it is very difficult at this point in time to say which of the potential early cancer detection tests out there will achieve broad coverage by payers. (Getty (Guardant) Tr. 2661–62.)

Response to Finding No. 1821

The proposed finding is misleading to the extent it implies that Guardant does not plan to seek payer coverage for LUNAR-2 in the future or that Guardant will not receive payer coverage for LUNAR-2. [redacted] Additionally, the proposed finding is misleading to the extent that [redacted] Therefore, this Court should disregard the proposed finding.

1822. Mr. Getty admitted that Guardant cannot assure that it will continue to compete effectively: Guardant's product development process involves a high degree of risk; commercialization of LUNAR-2 is not guaranteed; LUNAR-2 may not perform as expected; the data that Guardant is seeking to develop now to validate LUNAR-2 may not validate it as hoped for; Guardant may not be able to produce the evidence that it needs to ensure that it gets private payer and Medicare coverage for LUNAR-2; and even if LUNAR-2 performs as Guardant hopes it will, it may not achieve market acceptance. (Getty (Guardant) Tr. 2664–65.)

Response to Finding No. 1822

The proposed finding is vague because it fails to define or describe what "compete effectively" means.

The proposed finding is misleading and incorrect to the extent it implies that Mr. Getty testified that "Guardant cannot assure that it will continue to compete effectively." Respondents' counsel asked Mr. Getty "And Guardant cannot assure that it will continue to keep – compete effectively; right?" to which Mr. Getty answered, "I don't think any company can." (Getty (Guardant) Tr. 2664). Thus, Mr. Getty never testified that he believes that Guardant can't

effectively compete in the future, but simply that no one can guarantee its competitive nature in the future. Respondents twist Mr. Getty's testimony to best fit their narrative and in the process misconstrue what Mr. Getty testified to.

[redacted]

1823. Alleged foreclosure. Complaint Counsel contends that Illumina is the only viable NGS platform for MCED test developers, including Guardant, but Mr. Getty admitted that Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms also provide NGS platforms that could be used for liquid biopsy testing. (Getty (Guardant) Tr. 2642.)

Response to Finding No. 1823

The proposed finding is vague because it fails to define or explain who "other companies developing next-generation sequencing platforms" includes.

The proposed finding is incorrect, egregiously misleading and against the weight of the evidence to the extent it implies that Getty testified that Thermo Fisher is an option for its MCED test or that Guardant has any other viable NGS alternative to switch to for their MCED test. The testimony that Respondents cite relates to a portion of Guardant's 10-K in which Guardant refers to Thermo Fisher as a "competitor[] within the liquid biopsy space," meaning that Thermo Fisher offers tests itself in competition with Guardant. (PX0060 at 14). Rather, Mr. Getty testified at trial that Guardant cannot run its MCED test on a Thermo Fisher

sequencer. (Getty (Guardant) Tr. 2688). Mr. Getty also testified that there are no other companies, besides Illumina, developing NGS platforms at this time that Guardant could use for its MCED test. (Getty (Guardant) Tr. 2688).

Guardant cannot use Thermo Fisher's NGS platform because [redacted]

[redacted]

The proposed finding is misleading to the extent it implies that Guardant can use long-read NGS sequencing platforms as a viable alternative to Illumina's NGS platform. Long-read NGS is not a viable alternative to Illumina's NGS platform. [redacted]

1824. Complaint Counsel contends that Illumina is essential to the development and commercialization of MCED tests, but Mr. Getty admitted that LUNAR-2 assay is proprietary to Guardant and Illumina did not help Guardant develop the LUNAR-2 assay, did not contribute to the scientific effort Guardant undertook in connection with the LUNAR-2 assay, and did not brainstorm with Guardant on how it could improve the LUNAR-2 assay; Illumina has not been involved in any FDA review or consideration of the LUNAR-2 assay; and Guardant will be the sponsor of a PMA application for the LUNAR-2 assay as a sole-source laboratory. (Getty (Guardant) Tr. 2645–46.)

Response to Finding No. 1824

The proposed finding is vague because the following terms are undefined: "essential," "FDA… consideration," "sponsor," and "sole-source laboratory."

The proposed finding is misleading to the extent it implies that Illumina's NGS platform is not "essential to the development and commercialization of" Guardant's MCED test. Illumina's NGS platform is "essential to the development and commercialization" of Guardant's MCED test because Illumina's NGS technology is foundational to LUNAR-2 and there is no

alternative NGS platform Guardant could use to power its MCED test. (Getty (Guardant) Tr. 2645) (Illumina is "the underlying NGS technology that enables [Guardant's MCED test]"); *see* CCFF ¶¶ 1106-39) [redacted] Mr. Getty testified that a portion of Guardant's product "portfolio is dependent on Illumina and their sequencers and reagents, service." (Getty (Guardant) Tr. 2517). Mr. Getty testified that nothing is comparable to Illumina's NGS platforms. (Getty (Guardant) Tr. 2510). Ultimately, "[w]ithout [Illumina], Guardant doesn't exist." (PX7040 (Getty (Guardant) IHT at 190)).

The proposed finding is misleading to the extent it implies that Guardant does not rely on Illumina for assistance, service, and support when developing and commercializing their products. [redacted] Guardant relies on Illumina for servicing of machines, regulatory support, and the "development and finetuning of our technology." (Getty (Guardant) Tr. 2509). Mr. Getty testified that Illumina's instruments are "highly tuned machines," so "in order for us to maximize the value of

those, we certainly need to know from Illumina representatives how those might be best deployed." (Getty (Guardant) Tr. 2514). Mr. Getty testified that "without [Illumina's] sequencers [and] without the service that Illumina provides to keep them in good working order, [Guardant] would be unable to run [blood samples of patients] and deliver the final product to patients." (Getty (Guardant) Tr. 2685-86). "[T]here's a symbiotic relationship between Guardant Health and our activity and Illumina's activities in terms of making sure we're maximizing the value of the products they have delivered to us." (Getty (Guardant) Tr. 2509).

The proposed finding is misleading to the extent it implies that "Illumina has not been involved in any FDA review or consideration of the LUNAR-2 assay." Mr. Getty was asked by Respondents' counsel "[a]nd Illumina has not been involved in any FDA review or consideration of the LUNAR-2 assay; right?" to which Mr. Getty answered "[t]here hasn't been any FDA review yet." (Getty (Guardant) Tr. 2645). Respondents twist Mr. Getty's testimony make it seem like Illumina has withheld assistance to Guardant regard FDA review. When in fact simply no FDA review process has begun yet for LUNAR-2. Thus, the proposed finding is misleading and should be disregarded.

1825.

[redacted]

Response to Finding No. 1825

[redacted]

[redacted]

1826. Mr. Getty also admitted that it is difficult to predict whether clinicians will choose to order LUNAR-2 or Galleri; the patient's out-of-pocket cost will be a factor for primary care physicians choosing among cancer screening tests; workflow within primary care physicians' office will also be of importance; the performance characteristics of the various cancer screening tests will also be important to any clinician who is actually going to utilize these technologies; the number of cancers that the tests screen for likely will be part of the decision. (Getty (Guardant) Tr. 2670–72, 2674.)

Response to Finding No. 1826

The proposed finding is misleading and incorrect because Respondents fail to provide the full context of Mr. Getty's testimony. Respondents' counsel asked Mr. Getty, "Now, you plan that primary care providers will be the ones to order LUNAR-2; right?" to which Mr. Getty answered "That is a – the main target for our activities. Yes." (Getty (Guardant) Tr. 2670). Respondents' counsel then asked Mr. Getty "And you expect that primary care providers will choose between LUNAR-2 and Galleri; right?" to which Mr. Getty answered "I expect they'll choose between a multitude of tests, but Galleri may be one of them. Yes." (Getty (Guardant) Tr. 2670). Mr. Getty also testified that a primary care physician's decision to select one test over another tests will "likely not [] be a simple decision." (Getty (Guardant) Tr. 2670). Thus, there are a number of factors, in addition to the ones Respondents highlight in this finding, that primary care physicians will take into account when deciding which test to use.

The proposed finding is misleading and incorrect to the extent it implies that Mr. Getty testified that "it is difficult to predict whether clinicians will choose to order LUNAR-2 or Galleri." Respondents' counsel asked Mr. Getty "[s]itting here today, you would agree it's difficult to predict whether clinicals will choose to order LUNAR-2 or Galleri; right?" to which Mr. Getty answered, "[t]here are insights that we can gather through market research that help us

to make an informed prediction, but certainly nothing is a guarantee." (Getty (Guardant) Tr. 2672). Respondents pick and choose the snippets of Mr. Getty's testimony that best fit their narrative and in the process misconstrue what Mr. Getty testified to. Therefore, this Court should disregard the proposed finding.

1827. Open Offer and Negotiations with Illumina. Complaint Counsel contends that Illumina's Open Offer is insufficient to resolve its concerns about the reunion of Illumina and Grail, but Mr. Getty admitted that Guardant has not engaged with Illumina about the Open Offer. (Getty (Guardant) Tr. 2668.)

Response to Finding No. 1827

The proposed finding is vague and against the weight of the evidence. The proposed finding is vague because it fails define or describe what "has not engaged" means. Moreover, the proposed finding is misleading and against the weight of the evidence to the extent it implies that Guardant has not had discussions with Illumina regarding a long-term supply agreement. [redacted]

[redacted]

1828. [redacted]

Response to Finding No. 1828

[redacted]

[redacted]

[redacted]

1829. Complaint Counsel contends that the Open Offer contains holes and is difficult to enforce, but Mr. Getty admitted that Guardant has never told Illumina in substance that Amendment 5 is unenforceable and worthless. (Getty (Guardant) Tr. 2668.) [redacted]

Response to Finding No. 1829

[redacted]

[redacted]

[redacted]

1830. Efficiencies. Complaint Counsel contends the Transaction will not generate efficiencies, but Mr. Getty admitted the right multicancer early detection test may help to reduce mortality and the sooner a right multicancer early detection test becomes available on a widespread basis to the public, the better. (Getty (Guardant) Tr. 2637–38.)

Response to Finding No. 1830

The proposed finding is vague because it fails to define or describe what "efficiencies" mean. The proposed finding is also vague because it fails to explain what "a right multicancer early detect test" means.

The proposed finding is misleading because it fails to mention that Mr. Getty also testified that if the "wrong test" becomes available on a widespread basis to the public that "unfortunately, would cause harm." (Getty (Guardant) Tr. 2638). Thus, Respondents pick and choose the snippets of Mr. Getty's testimony that best fit their narrative and in the process misconstrue what Mr. Getty testified to. Therefore, this Court should disregard the proposed finding.

1831. Bias. Complaint Counsel presented Mr. Getty as an unbiased witness, but Mr. Getty admitted that Guardant sees GRAIL as a competitor: there are first-mover advantages associated with being the first multicancer early detection test to market; it may be worth double the market share to be the first mover; and Guardant is not as far along as GRAIL on the path towards commercialization of a multicancer early detection test. Getty (Guardant) Tr. 2639–40.) Mr. Getty is a competitive person and would like to see Guardant come out on top in the marketplace of a multicancer early detection test. (Getty (Guardant) Tr. 2639–40).

Response to Finding No. 1831

The proposed finding is misleading and incorrect because Mr. Getty did not testify that he would ultimately like to see Guardant prevail over Grail in the market place. Mr. Getty testified that he would "like to see the mortality curve get bent down, frankly, in cancer, and I think the best test would do that. I think the underlying premise of being first is a portion of that

argument, but there are many reasons why tests or therapeutics are valuable for patients and are adopted." (Getty (Guardant) Tr. 2640).

The proposed finding is misleading to the extent it implies that [redacted]

7. **Kenneth Chahine (Helio)**

a. Background

1832. Dr. Chahine was the Chief Executive Officer of Helio Health until June 2021. (Chahine (Helio) Tr. 999.)

Response to Finding No. 1832

Complaint Counsel does not disagree with the proposed finding.

1833. Dr. Chahine is currently working for a New York based start-up, code name Cedar, and is the advisor to Helio Health. (Chahine (Helio) Tr. 998.)

Response to Finding No. 1833

Complaint Counsel does not disagree with the proposed finding.

1834. Dr. Chahine was previously employed at Ancestry.com as the Executive Vice President and General Manager at AncestryDNA. (Chahine (Helio) Tr. 1002.)

Response to Finding No. 1834

Complaint Counsel does not disagree with the proposed finding.

b. Testimony

1835. Alleged Relevant Market. [redacted]

Response to Finding No. 1835

This proposed finding is misleading to the extent it insinuates that Helio is not a MCED test developer. Dr. Chahine testified that [redacted] (CCFF ¶ 2501). Therefore, this Court should disregard the proposed finding.

1836. [redacted]

[redacted]

Response to Finding No. 1836

[redacted]

[redacted]

1837. [redacted]

Response to Finding No. 1837

[redacted]

[redacted]

[redacted]

[redacted]

1838. [redacted]

Response to Finding No. 1838

[redacted]

[redacted]

[redacted]

1839. Dr. Chahine admitted that the success of various early cancer screening tests will depend on various technical, scientific and regulatory variables; each of the MCED tests in development could ultimately be differentiated from one another, such as focusing on different types of cancers, using different technologies, having different levels of sensitivity or specificity, being approved by the FDA for different intended uses and being covered by third-party payers for different uses; there is no certainty about which MCED tests in development will actually come to market, which MCED tests in development will actually compete with GRAIL's multicancer test or which of the MCED tests in development will be the market leaders in the future; there is no way to predict five, ten or fifteen years from now which of these various companies developing early cancer screening tests is actually going to be successful in bringing an early cancer screening test to market; Helio's strategy in pursuing a series of tests for specific cancers, particularly liver cancer, potentially differentiates Helio from GRAIL and Thrive, who are developing blood tests to detect multiple types of cancer. (Chahine (Helio) Tr. 1125–27.)

Response to Finding No. 1839

[redacted]

[redacted]

1840. Alleged foreclosure. [redacted]

Response to Finding No. 1840

[redacted]

[redacted]

[redacted]

1841. [redacted]

[redacted]

Response to Finding No. 1841

[redacted]

1842. [redacted]

Response to Finding No. 1842

[redacted]

[redacted]

1843. The Transaction. [redacted]

[redacted]

Response to Finding No. 1843

[redacted]

1844. Efficiencies. Complaint Counsel contends that the Transaction will not generate efficiencies, but Dr. Chahine admitted that because the FDA follows precedence, if one company's MCED test is approved by the FDA, it could potentially make it easier for another company to bring a different MCED test to market; if GRAIL accelerates the process by which it gets FDA approval for its MCED test, that could possibly accelerate the process by which other companies get FDA approval for their cancer screening tests; that if one company's MCED test gets covered or reimbursed by Medicare, that can grease the skids for other companies who want to get reimbursement for similar tests, and so they will have an easier time; and one of the advantages of being second and following someone else who's ahead is it makes it easier to get reimbursement coverage. (Chahine (Helio) Tr. 1128–32.)

Response to Finding No. 1844

[redacted]

[redacted]

[redacted]

1845. Dr. Chahine admitted that if GRAIL gets its MCED test out to market at scale, that would be a positive for society and would potentially save lives; and the sooner any company gets its early cancer screening tests to market, the sooner those societal benefits will be realized. (Chahine (Helio) Tr. 1132–33.)

Response to Finding No. 1845

[redacted]

[redacted]

[redacted]

8. **Matthew Strom (Morgan Stanley)**

a. Background

1846. Matthew Strom is a managing director in Morgan Stanley's healthcare investment banking group. Morgan Stanley served as GRAIL's exclusive financial advisor from 2017 through Illumina's acquisition of GRAIL in 2021. (Strom (Morgan Stanley) Tr. 3473.)

Response to Finding No. 1846

Complaint Counsel has no specific response to this proposed finding.

1847. Specific to Illumina's acquisition of GRAIL, Morgan Stanley was asked to help GRAIL negotiate the transaction with Illumina and to evaluate potential alternatives, such as an IPO. Morgan Stanley was also tasked with providing financial perspective to GRAIL's board through valuation considerations and due diligence on the transaction. (Strom (Morgan Stanley) Tr. 3474.)

Response to Finding No. 1847

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1848. Alleged Relevant Market. Complaint Counsel contends that several companies are working on MCED tests, but Mr. Strom confirmed that Morgan Stanley's report shows that the large-scale clinical trials by Guardant Health, Exact Sciences and Freenome are all in colon cancer; there is no company other than GRAIL offering an MCED test relying on NGS in the market today. (Strom (Morgan Stanley) Tr. 3595–96.)

Response to Finding No. 1848

The proposed finding is vague, confusing, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define and/or quantify the terms "several," "large-scale," and "the market." The proposed finding is confusing. With their proposed finding, Respondents appear to attempt to refute "Complaint Counsel['s contention] that several companies are working on MCED tests." Yet Respondents offer nothing to refute this contention. Instead, they claim that "Morgan

Stanley's report" shows certain companies' clinical trials concern colon cancer and that "no company other than GRAIL [is] offering an MCED test relying on NGS in the market today." Neither of these claims refute the contention "that several companies are working on MCED tests."

The proposed finding is unreliable for at least two reasons. First, rather than referencing ordinary course evidence to substantiate these claims regarding Guardant, Exact, and Freenome, Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded. Second, the proposed finding is unreliable because Mr. Strom does not have foundation to discuss whether "several companies are working on MCED tests." [redacted] It is unclear what basis, if any, he has to opine regarding the plans of other MCED test developers or whether "several companies are working on MCED tests." Similarly, it is unclear what information serves as the basis for the "Morgan Stanley[] report" discussed in this finding, which Respondents do not cite to. It is unclear whether this "report" contained any non-public information or whether there is any expectation that this report would accurately reflect the plans of other MCED test developers.

The proposed finding is also misleading and against the weight of the evidence, insofar as it implies that companies are not currently competing with Grail in the MCED test market. The evidence provided by MCED test developers, which Morgan Stanley does not have access to, clearly indicates that other MCED tests are and will be competing with Grail's Galleri test. For

example, evidence indicates that [redacted]

1849. [redacted]

Response to Finding No. 1849

[redacted]

[redacted]

1850. Alleged Foreclosure. Complaint Counsel contends that there are no alternatives to Illumina in the upstream NGS market, but Mr. Strom confirmed that the funding environment for NGS remains very robust: there was an announcement that ONT just raised a fairly significant amount of capital through an IPO in the London Stock Exchange and have publicly announced that they have launched that IPO to raise $350 million at a $3.5 billion valuation; Morgan Stanley also works with a number of clients in the NGS space in the private market who have raised private capital and are potentially evaluating accessing the public markets; and investors continue to be quite interested in the NGS space given the vast sort of opportunity out there. (Strom (Morgan Stanley) Tr. 3476–77, 3489–90.)

Response to Finding No. 1850

The proposed finding is confusing, vague, unreliable, and should be disregarded by this Court. The proposed finding is confusing. Complaint Counsel agrees that "there are no alternatives to Illumina in the upstream NGS market." But Mr. Strom's testimony that "the funding environment for NGS remains very robust" has no bearing whatsoever on whether there

are upstream alternatives to Illumina. Moreover, the fact (even if it were reliable) that "ONT just raised a fairly significant amount of capital" does not mean, as Respondents appear to suggest, that ONT will become an upstream alternative to Illumina. This statement provides no basis to make such an assumption.

The proposed finding is also vague. Respondents fail to define the terms "very robust," "fairly significant amount of capital," "a number of clients," "potentially evaluating accessing the public markets," "quite interested," and "vast sort of opportunity out there." In particular, it means nothing that someone is "potentially evaluating accessing the public markets."

The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate these claims regarding whether "Morgan Stanley also works with a number of clients in the NGS space in the private market who have raised private capital and are potentially evaluating accessing the public markets," Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded. Similarly, it is unclear who the "number of [Morgan Stanley] clients in the NGS space" are, what that number is, and what Morgan Stanley's basis is in claiming that those clients are "potentially evaluating accessing the public markets." Therefore, this Court should disregard the proposed finding.

1851. While Complaint Counsel claims that the Transaction would inhibit innovation and entry into the MCED space, but Mr. Strom confirmed that there is significant investor interest in the cancer diagnostics space, which is probably the most interesting subsector of diagnostics to investors; Morgan Stanley has not seen investment interest in the diagnostics space slow down at all since Illumina announced its intention to acquire GRAIL in around September 2020: there has been a robust level of activity in the diagnostics space, both in the public and private markets and a lot of investors have seen the exit opportunity that GRAIL's investors had as a positive and validating moment for this space; Morgan Stanley has observed

increased investor interest in other companies that are working in the cancer diagnostics space since the Illumina-GRAIL acquisition was announced; Natera's stock actually increased in value since Illumina closed the transaction and acquisition of GRAIL on August 18, 2021; and Guardant's stock price continues to have good momentum as well. (Strom (Morgan Stanley) Tr. 3478–80.)

Response to Finding No. 1851

The proposed finding is vague, confusing, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "significant investor interest," "probably the most interesting subsector," "diagnostics space," "robust level," "a lot of investors," "the exit opportunity," "a positive and validating moment," "this space," increased investor interest," "other companies," and "good momentum." In particular, it is unclear and confusing whether and to what degree "the diagnostics space" includes "the MCED space," and therefore it is unclear what bearing "a robust level of activity in the diagnostics space" has on the Transaction's inhibition of innovation and entry into the MCED space. Similarly, it is unclear what "Natera's stock actually increase[ing] in value" or Guardant's stock "hav[ing] good momentum" has to do with whether the Transaction would inhibit innovation and entry into the MCED space.

More generally, the proposed finding is confusing insofar as it implies that "a robust level of activity in the diagnostics space" means that the Transaction will not "inhibit innovation and entry into the MCED space."

The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate these claims regarding whether "there has been a robust level of activity in the diagnostics space," Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded.

Lastly, the proposed finding is misleading insofar as it suggests that the Transaction "will [not] inhibit innovation and entry into the MCED space." Such an implication is against the weight of the evidence, which demonstrates, among other things, that [redacted]

Therefore, this Court should disregard the proposed finding.

1852. NIPT. While Complaint Counsel claims that Illumina has successfully foreclosed rivals in the NIPT market, Mr. Strom confirmed that in the last six to nine months, the various societies that help put out clinical guidelines around reimbursement for different tests have recommended that all women who are pregnant receive NIPT testing and be reimbursed for that use—whereas before it was just for high-risk-deemed pregnancies—which was a meaningful growth in number of patients that it was recommended for and thus recommended to be reimbursed for; since Illumina acquired Verinata, the annual amount of NIPT testing that actually gets to patients has increased. (Strom (Morgan Stanley) Tr. 3486–87, 3492.)

Response to Finding No. 1852

The proposed finding is confusing, against the weight of the evidence, vague, unreliable, and should be disregarded by this Court. The proposed finding is confusing. Whether "in the last six to nine months, the various societies that help put out clinical guidelines . . . recommended that all women who are pregnant receive NIPT testing," has no discernable bearing on whether "Illumina has successfully foreclosed rivals in the NIPT market." To the extent the proposed finding suggests that Illumina has not harmed downstream rivals in the NIPT market, the proposed finding against the weight of the evidence, which demonstrates that, for example, [redacted] (CCFF ¶¶ 4081-4164).

The proposed finding is vague. Respondents fail to define the terms "successfully foreclosed," "the last six to nine months," "the various societies," "different tests," "meaningful growth," "the annual amount of NIPT testing that actually gets to patients," and "increased." In particular, it is unclear whether "the annual amount of NIPT testing that actually gets to patients" is different from increased NIPT testing. For example, it is unclear whether Respondents and Mr. Strom mean that there is more NIPT testing being done, or if there are the same number of NIPT tests, but more of them are "actually get[ting] to patients."

The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate these claims regarding whether there has been an increase in NIPT testing and reimbursement for it, Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded.

1853. Mr. Strom confirmed that Natera's test has the biggest share of the NIPT market; Natera has been able to significantly increase its market share in NIPT over time despite the fact that Illumina owns Verinata; and Verinata's market share has decreased in the NIPT market in the time since Illumina acquired Verinata. (Strom (Morgan Stanley) Tr. 3492.)

Response to Finding No. 1853

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "the biggest share," "significantly increase," and "decreased."

The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate these claims regarding market shares in the NIPT market, Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability

of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading insofar as it implies, because "Natera's test has the biggest share of the NIPT market" and "Verinata's market share has decreased in the NIPT market," that Illumina has not successfully foreclosed rivals in the NIPT market. Such an implication is against the weight of the evidence, which demonstrates that [redacted] (CCFF ¶¶ 4081-4164). Therefore, this Court should disregard the proposed finding.

1854. Mr. Strom confirmed that the costs of Illumina's sequencing products for NIPT applications has decreased significantly since Illumina acquired Verinata. (Strom (Morgan Stanley) Tr. 3492.)

Response to Finding No. 1854

The proposed finding is vague, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is vague. Respondents fail to define the terms "NIPT applications" and "decreased significantly." In particular, the phrase "decreased significantly" communicates no factual information at all, and its meaning is entirely dependent on what Mr. Strom, or Respondents, consider to be "significant." The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate these claims regarding market shares in the NIPT market, Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded. The proposed finding is misleading, insofar as it implies that

Illumina has not successfully foreclosed rivals in the NIPT market because "the costs of Illumina's sequencing products for NIPT applications has decreased." Such an implication is against the weight of the evidence, which demonstrates that [redacted] (CCFF ¶¶ 4081-4164). Therefore, this Court should disregard the proposed finding.

1855. Efficiencies. [redacted]

Response to Finding No. 1855

[redacted]

[redacted]

[redacted]

1856. [redacted]

Response to Finding No. 1856

[redacted]

[redacted]

1857. [redacted]

Response to Finding No. 1857

[redacted]

[redacted]

1858. [redacted]

Response to Finding No. 1858

[redacted]

[redacted]

1859. [redacted]

Response to Finding No. 1859

[redacted]

[redacted]

1860. [redacted]

Response to Finding No. 1860

[redacted]

[redacted]

1861. [redacted]

Response to Finding No. 1861

[redacted]

[redacted]

1862. Mr. Strom confirmed that in Morgan Stanley's view, GRAIL needed to make it clear to investors that: GRAIL has used significant capital in the past and that they should expect that GRAIL will continue to use significant capital in the future; based on the market capitalization as well as cash balance and cash flow of Illumina, the transaction at issue today provide sufficient capital to provide for the needs of GRAIL given these significant net losses in the foreseeable future; GRAIL did not have institutional experience generating revenue from products and that in the near term any revenue GRAIL did generate would be too small to offset or cause it to break even on its level of expenses; and the Illumina-GRAIL transaction provides sufficient capital to provide for GRAIL's needs of significant capital in the foreseeable future. (Strom (Morgan Stanley) Tr. 3597–99.)

Response to Finding No. 1862

The proposed finding is incorrect, misstates testimony, is unreliable, and should be disregarded by this Court. The proposed finding is incorrect and misstates Mr. Strom's testimony. Respondents contend that "GRAIL needed to make it clear to investors that . . . the transaction . . . provide [sic] sufficient capital" for Grail and that "the Illumina-GRAIL transaction provides sufficient capital to provide for GRAIL's needs[.]" This is not Mr. Strom's testimony. He did not testify that Grail "needed to make it clear to investors that" the Transaction would provide for Grail's capital needs, setting aside the issue of whether that contention is accurate.

The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate this proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded.

1863. Efficiencies. Mr. Strom testified that the transaction would lead to the elimination of GRAIL's royalty and accelerate market access to Galleri. (Strom (Morgan Stanley) Tr. 3599.)

Response to Finding No. 1863

The proposed finding is unsupported, unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is unsupported. In the cited portion of Mr. Strom's testimony, he does not discuss whether "the transaction [sic] would . . . acceleration market access to Galleri." The proposed finding is vague. Respondents fail to define the terms "accelerate" and "market access." The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate this proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading, insofar as it implies that the Transaction "would . . . accelerate market access to Galleri." Such an implication is against the weight of the evidence,

[redacted]

More to the point, Respondents, in this proposed finding and throughout this litigation, have not provided sufficient information to verify the claim that the Transaction will "accelerate market access to Galleri," nor have they demonstrated that such a claim is merger specific. A cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating their claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. Therefore, this Court should disregard the proposed finding.

1864. *Elimination of Royalty.* [redacted]

Response to Finding No. 1864

[redacted]

[redacted]

1865. [redacted]

Response to Finding No. 1865

[redacted]

[redacted]

1866. [redacted]

Response to Finding No. 1866

[redacted]

[redacted]

1867. [redacted]

Response to Finding No. 1867

[redacted]

[redacted]

1868. Mr. Strom testified that in Morgan Stanley's view, the proposed Illumina acquisition would remove that risk posed by the royalties owed to Illumina (Strom (Morgan Stanley) Tr. 3536); the transaction eliminates the risk of the high-single-digit royalties owed to GRAIL and the impediment they posed to GRAIL's efforts to obtain profitability (Strom (Morgan Stanley) Tr. 3597–99).

Response to Finding No. 1868

The proposed finding is unreliable, misleading, against the weight of the evidence, and should be disregarded by this Court. The proposed finding is unreliable. Rather than referencing ordinary course evidence to substantiate this proposed finding, Respondents cite only to the unfounded, self-serving testimony of a single Morgan Stanley representative, which is uncorroborated by any ordinary course documents or analysis. Given the inherent unreliability of this testimony as well as lack of foundation or explanation for Mr. Strom's base conjecture, this proposed finding of fact should be disregarded.

The proposed finding is misleading, insofar as it implies that [redacted] (CCFF ¶¶ 5757-5777). Therefore,

this Court should disregard the proposed finding.

1869. *Acceleration of Market Access to Galleri.* [redacted]

Response to Finding No. 1869

[redacted]

[redacted]

1870. [redacted]

Response to Finding No. 1870

[redacted]

[redacted]

[redacted]

9. **Matthew Rabinowitz (Natera)**

a. Background

1871. Dr. Rabinowitz serves as the executive chairman of Natera, a position he has held since 2019. (Rabinowitz (Natera) Tr. 284–85.)

Response to Finding No. 1871

The proposed finding is incomplete as it omits Dr. Rabinowitz other valuable experience, like being the co-founder and CEO of Natera. (PX7054 (Rabinowitz (Natera) IHT at 16)). Therefore, this Court should disregard the proposed finding.

1872. As chairman, Rabinowitz consults on issues concerning technology, strategy, and business development. (Rabinowitz (Natera) Tr. 286.)

Response to Finding No. 1872

The proposed finding is misleading and incorrect as it misstates Dr. Rabinowitz's testimony. Dr. Rabinowitz did not testify that he "consults" on these issues Respondents list. Rather, Dr. Rabinowitz testified that he "oversee[s] and work[s] with the company on a range of issues. I work on the technology, the strategy, key business development decisions. As chairman of the board, I coordinate a lot of the board activities and work with Steve during the board meetings. Steve is the CEO. I'm involved in most of the key issues that Natera needs to decide or strategize about, but I'm not involved as the CEO is in a lot of the day-to-day issues, such as, you know, HR, talking to investors at the same level. A lot of the day-to-day operations fall to the CEO and the chief operating officer." (Rabinowitz (Natera) Tr. 286). Therefore, this Court should disregard the proposed finding.

b. Testimony

1873. Alleged Relevant Market. [redacted]

Response to Finding No. 1873

[redacted]

[redacted]

[redacted]

1874. [redacted]

Response to Finding No. 1874

[redacted]

[redacted]

[redacted]

1875. [redacted]

Response to Finding No. 1875

[redacted]

[redacted]

1876. [redacted]

Response to Finding No. 1876

[redacted]

[redacted]

[redacted]

1877. [redacted]

Response to Finding No. 1877

[redacted]

[redacted]

1878. Dr. Rabinowitz admitted that Natera told its shareholders that there are significant risks associated with Natera's development of an MCED test, including that:

Response to Finding No. 1878

The proposed finding is incomplete and unsupported because Respondents fail to note what "significant risks" Natera told to its shareholders. Additionally, Respondents fail to provide a citation which supports this proposed finding. Thus, this finding should be disregarded.

1878.1 [redacted]

Response to Finding No. 1878.1

[redacted]

[redacted]

1878.2 [redacted]

Response to Finding No. 1878.2

[redacted]

[redacted]

1878.3 [redacted]

Response to Finding No. 1878.3

[redacted]

[redacted]

[redacted]

[redacted]

1878.4 [redacted]

Response to Finding No. 1878.4

[redacted]

[redacted]

1878.5 [redacted]

Response to Finding No. 1878.5

[redacted]

[redacted]

1879. Alleged Foreclosure. [redacted]

Response to Finding No. 1879

[redacted]

[redacted]

[redacted]

1880. [redacted]

Response to Finding No. 1880

[redacted]

[redacted]

1881. [redacted]

[redacted]

Response to Finding No. 1881

[redacted]

[redacted]

[redacted]

[redacted]

1881.1 In addition, Guardant has accused Natera of making false comparisons of its MRD test to Guardant's MRD test "[w]ith little or no concern for the [colorectal cancer] patients who could be harmed". (RX3297 (*Guardant Health v. Natera*, 3:21-cv-04062, Dkt. No. 1) ¶ 3.) CareDx, a rival to Natera in kidney transplant testing, has accused Natera of "making various false and misleading claims that [Natera's test] is superior to CareDx's AlloSure" kidney transplant test". RX3096 (*CareDx, Inc. v. Natera*, 1:19-cv-00662, Dkt. No. 1) ¶ 3.) [redacted]

Response to Finding No. 1881.1

[redacted]

[redacted]

[redacted]

1882. Open Offer. [redacted]

Response to Finding No. 1882

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1883. [redacted]

Response to Finding No. 1883

[redacted]

[redacted]

[redacted]

[redacted]

1884. [redacted]

Response to Finding No. 1884

[redacted]

[redacted]

[redacted]

1885. Efficiencies. [redacted]

Response to Finding No. 1885

[redacted]

1886. Bias. [redacted]

Response to Finding No. 1886

[redacted]

[redacted]

10. **Gary Gao (Singlera)**

a. Background

1887. Dr. Yuan (Gary) Gao is a board member and a scientific advisor of Singlera and had served as Singlera's chairman from beginning of the company in July 2014 until June 2020. (Gao (Singlera) Tr. 2871.)

Response to Finding No. 1887

The proposed finding is confusing to the extent it suggests Dr. Gary Gao's position as a

scientific advisor to Singlera ended in June 2020. Dr. Gao still currently serves as a Board Member and Scientific Advisor to Singlera. [redacted] Complaint Counsel does not disagree that Dr. Gao served as the Singlera's Chairman from July 2014 to June 2020.

b. Testimony

1888. Alleged Relevant Market. Complaint Counsel contends that Singlera is working on an MCED test that will directly compete with Galleri, but Dr. Gao admitted that Singlera does not have an MCED test on the market; the ColonES test that Singlera is currently developing has a specific focus on early detection of only colorectal cancer in asymptomatic patients; Singlera does not have any clinical trial evidence that ColonES can detect more than one cancer; Singlera's PanSeer test can only detect five cancers, including lung, liver, esophageal, gastric, and colorectal cancers, for asymptomatic patients; Singlera's publication on PanSeer did not mention early detections of any other cancers; Singlera does not currently offer any form of the PanSeer early detection test for use in the U.S.; Singlera is a long way away from even starting clinical trials for PanSeer; Singlera has not even had discussions with the FDA about PanSeer; Singlera has not even begun designing a clinical trial plan for PanSeer or engaged FDA consultants for any FDA submissions related to PanSeer as it did for ColonES. (Gao (Singlera) Tr. 2914–15, 2917; 2917–18; 2926–27, 2942–43, 2949.)

Response to Finding No. 1888

This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Additionally, the proposed finding is vague, confusing, unsupported, incomplete, misleading, incorrect, and against the weight of the evidence. Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' string citation at the end of their recitation of unrelated statements does not provide clear support for any individual statement. In order to address the many statements Respondents make, Complaint Counsel has broken out each separately below.

Respondents' first statement reads: "Complaint Counsel contends that Singlera is working on an MCED test that will directly compete with Galleri, but Dr. Gao admitted that Singlera does not have an MCED test on the market[.]" This statement is confusing, misleading, and incorrect. Respondents incorrectly associate working on an MCED test with "hav[ing] an MCED test on the market." Highlighting that Singlera has been actively developing an MCED test does not imply they have an MCED test on the market, which Complaint Counsel has not alleged.

The next two statements read: "the ColonES test that Singlera is currently developing has a specific focus on early detection of only colorectal cancer in asymptomatic patients; Singlera does not have any clinical trial evidence that ColonES can detect more than one cancer[.]" This statement is also confusing and misleading to the extent Respondents are drawing a connection between Singlera's MCED test, the PanSeer, and its colorectal cancer screening test, the ColonES. Although Singlera is developing both tests, and they both rely on DNA methylation to detect cancer, these two cancer screening tests are separate products. (PX7042 (Gao (Singlera) IHT at 117, 119-20). Further, the ColonES is intentionally designed as a single-cancer test to detect colorectal cancer only. (Gao (Singlera) Tr. 2873-74).

The next statements read: "Singlera's PanSeer test can only detect five cancers, including lung, liver, esophageal, gastric, and colorectal cancers, for asymptomatic patients; Singlera's publication on PanSeer did not mention early detections of any other cancers[.]" These statements are similarly vague, misleading, incomplete, unsupported, and against the weight of the evidence. Dr. Gao has made very clear the PanSeer is designed to detect all cancer types as a pan-cancer test. (*See, e.g.*, PX7102 (Gao (Singlera) Dep. at 94-95); Gao (Singlera) Tr. 2881). As Dr. Gao explained, Singlera performed a clinical study on its PanSeer MCED test that

focused on these five cancers—lung, liver, esophageal, gastric, and colorectal cancer—but any assertion these are the "only" cancers it can detect is plainly incorrect and against the weight of the evidence. (Gao (Singlera) Tr. 2881). [redacted] Respondent's second statement about Singlera's clinical study is also misleading to the extent it suggests Singlera sought to detect more than these five cancers in their study. As Dr. Gao testified, Singlera chose to focus on these five cancers first in its Taizhou Longitudinal study though the test is designed as a pan-cancer test. (Gao (Singlera) Tr. 2881-82, 2877-78).

The next statements read: "Singlera does not currently offer any form of the PanSeer early detection test for use in the U.S.; Singlera is a long way away from even starting clinical trials for PanSeer[.]" These statements are also misleading, incorrect, and against the weight of the evidence. Although Singlera does not currently offer the PanSeer test in the United States, their plans currently project they will be able to offer an LDT of the test in China in as early as 2023. (Gao (Singlera) Tr. 2892)). To the extent Respondents imply Singlera has not invested a significant amount of time and money into the development of the PanSeer test, this is also incorrect and against the weight of the evidence. Dr. Gao estimates that Singlera has already spent between $60-100 million on the development of the PanSeer test and has been in the development of the test for several years. (Gao (Singlera) Tr. 2865, 2869, 2888-89; PX7042 (Gao (Singlera) IHT at 15)). Respondents' use of the "long way away" is also vague and misleading without more information. Dr. Gao explained that Singlera currently expects to begin clinical trials on the PanSeer test in two to three years and plans to launch in the United States as an FDA approved test in 2028. (PX7042 (Gao (Singlera) IHT at 96, 100)).

The next statements read: "Singlera has not even had discussions with the FDA about PanSeer; Singlera has not even begun designing a clinical trial plan for PanSeer or engaged FDA consultants for any FDA submissions related to PanSeer as it did for ColonES." These statements are similarly misleading and incomplete. Dr. Gao clearly testified that Singlera plans to focus on completing the launch of its ColonES test while it continues the development of its PanSeer test. (PX7042 (Gao (Singlera) IHT at 119-20)). Without more information about when it becomes appropriate to begin engaging with FDA consultants, these statements do not provide information to the extent Respondents seek to imply that Singlera is still early in its development of its PanSeer test. The statements are also vague and incomplete because Respondents have not defined a "clinical trial plan" or "FDA submissions" or their relevance to Singlera's plans for further development of its PanSeer test. Therefore, this Court should disregard the proposed finding.

1889. Dr. Gao admitted that Singlera does not have a clear timeline for when Singlera will be able to launch a single cancer ColonES test in the U.S.; Singlera intends to seek FDA approval for the ColonES test, but expects it will be several years' time before ColonES obtains FDA approval; Singlera does not yet have a partnership lined up with a U.S.-based company to conduct a clinical trial for ColonES to obtain FDA approval and is at least one year away from even starting clinical trials in the U.S. for ColonES; and to obtain FDA approval, a clinical trial for ColonES could take three to four years; Dr. Gao does not believe that Singlera or any other test developer will have a colorectal or other early cancer detection test based on NGS on the market within the next three years. (Gao (Singlera) Tr. 2911–12, 2920–23.)

Response to Finding No. 1889

This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Additionally, the proposed finding is vague, confusing,

unsupported, incomplete, misleading, incorrect, and against the weight of the evidence. Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' string citation at the end of their recitation of unrelated statements does not provide clear support for any individual statement. Therefore, this Court should disregard the proposed finding.

1890. Dr. Gao also admitted that the investor have very little confidence in the current management team and in Dr. Gao being able to get FDA approval for the ColonES product and wanted to have a U.S. company directly involved in a clinical trial even of Singlera's colorectal cancer single screen test. (Gao (Singlera) Tr. 2910–11.)

Response to Finding No. 1890

The proposed finding is vague, confusing, unsupported, unreliable, misleading, and against the weight of the evidence. The proposed finding is vague and confusing because Respondents have not defined or identified "the investor," "the current management team," a "U.S. company," or a "single screen test." The proposed finding is unsupported to the extent Respondents intend to suggest Singlera's investors lack confidence in the ability of Singlera's management team, and specifically Dr. Gao, to obtain FDA approval for its ColonES test. Dr. Gary Gao's testimony does not support this conclusion. When asked whether "Singlera's investors have very little confidence in the ability of Singlera's management to get FDA approval of Singlera's products," Dr. Gao explicitly said "No. Why [would] they invest in the company if they don't have that belief?" (Gao (Singlera) Tr. 2910–11.) In response to a question from Respondent's counsel about Dr. Gao's testimony during his Investigational Hearing about Singlera's investors and their confidence in its management team to get approval of its ColonES test, Dr. Gao confirmed that was his testimony and began saying "I say that at that time, but I…" before being cut off by Respondent Counsel before he could finish responding. (Gao (Singlera) Tr. 2910–11.) When asked a second time whether "the investors

wanted to have a U.S. company directly involved in a clinical trial even of Singlera's colorectal cancer single screen [sic] test," Dr. Gao responded that this was merely "one of the alternatives." (Gao (Singlera) Tr. 2910–11.) The proposed finding is also further unsupported, misleading, and confusing to the extent Respondents are implying a U.S. company's involvement "in a clinical trial *even of* Singlera's colorectal cancer single screen test" suggests anything about Singlera's capabilities related to any other product. The testimony cited does not mention any test other than Singlera's ColonES test. (Gao (Singlera) Tr. 2910–11.) Therefore, this Court should disregard the proposed finding.

1891. Dr. Gao admitted that Singlera expects to launch the ColonES product first before it launches PanSeer; Singlera sees ColonES as the first top priority for commercialization because Dr. Gao thinks it is much easier to demonstrate the validity of single-cancer detection test than to demonstrate the validity of an MCED test; the regulatory pathway for approval of colorectal cancer is easier than the pathway for multiple cancer detection; the fact that Exact has already gone through an FDA approval process for colorectal cancer benefits other companies developing colorectal cancer screening tests; when the FDA ultimately approves an MCED test, it will make it easier for other MCED test developers to follow in the same footsteps. (Gao (Singlera) Tr. 2918–19, 2924.)

Response to Finding No. 1891

This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Additionally, the proposed finding is vague, confusing, unsupported, incomplete, misleading, incorrect, and against the weight of the evidence. Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' string citation at the end of their recitation of unrelated statements does not provide clear support for

any individual statement. Therefore, this Court should disregard the proposed finding.

1892. Dr. Gao believes that FDA would require a prospective pivotal trial for approval of a test for early cancer detection; doing clinical trials for a true MCED test will be a significant undertaking: a ten-year, 100,000–person study were only able to provide enough data to verify a five cancer test; to get FDA approval of a ten cancer test, a company would need to do a clinical study covering perhaps 200,000 people over eight to ten years; a company would need approximately ten years to do the clinical trial work to get the necessary results to get a ten cancer test approved by the FDA. (Gao (Singlera) Tr. 2919, 2924, 2926.)

Response to Finding No. 1892

This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Additionally, the proposed finding is vague, confusing, unsupported, incomplete, misleading, incorrect, and against the weight of the evidence. Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' string citation at the end of their recitation of unrelated statements does not provide clear support for any individual statement. Therefore, this Court should disregard the proposed finding.

1893. Alleged Foreclosure. Complaint Counsel contends the reunion of Illumina and Grail may foreclose GRAIL rivals, including Singlera, but Dr. Gao admitted that Singlera's PanSeer test was not designed to solely on Illumina equipment and it is compatible with Thermo Fisher's NGS systems, including the Ion Torrent S5. (Gao (Singlera) Tr. 2928.)

Response to Finding No. 1893

The proposed finding is vague, confusing, unsupported, against the weight of the evidence, misleading, incorrect, and unreliable. Respondents have structured this alleged "fact" by first attributing an argument to Complaint Counsel then making an unsupported statement

afterwards. Accordingly, the proposed finding should be disregarded because it is not a "finding of fact," but rather a legal conclusion in contravention of this Court's order and the Part 3 rules. (*See* Rule 3.46; Order on Post-Trial Findings). The proposed finding is also confusing, incomplete, and misleading because, as a legal argument, Respondent haven't attempted to explain the connection between Illumina's ability and incentive to foreclose Grail's rivals and the mischaracterized portion of Dr. Gary Gao's testimony about Thermo Fisher's sequencer.

To the extent Respondents are suggesting Thermo Fisher's NGS sequencer is a viable alternative to Illumina's NGS sequencers for MCED tests, such that test providers could switch to it, this proposed finding is also unquestionably against the weight of the evidence. Dr. Gao clearly testified that Singlera does not have a viable alternative to Illumina's NGS sequencer for its PanSeer test, (Gao (Singlera) Tr. 2901), and even described Illumina as the "800-pound gorilla" because it "control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies, too." (Gao (Singlera) Tr. 2951). Although Singlera evaluated the use of Thermo Fisher's NGS sequencers for use with its PanSeer test—when asked by Respondent's counsel if the PanSeer test is compatible with Thermo Fisher's NGS platforms, including its S5 sequencer, Dr. Gao merely said it was compatible "in theory." (Gao (Singlera) Tr. 2943). [redacted]

[redacted] Accordingly, this confusing proposed finding should be disregarded as against the weight of the evidence and thus wholly unreliable. Therefore, this Court should disregard the proposed finding.

1894. Dr. Gao estimates that it would take about six months to a year to switch from Illumina to Thermo Fisher NGS equipment for the PanSeer test; if Singlera were to switch to Thermo Fisher equipment today, it would not have to rerun any clinical trial that it had previously run for PanSeer, would not even need any bridging study to revalidate any PanSeer trial results, and would not disrupt any ongoing clinical trial work for PanSeer. (Gao (Singlera) Tr. 2942–43.)

Response to Finding No. 1894

The proposed finding is vague, confusing, unsupported, against the weight of the evidence, misleading, incorrect, and unreliable. The proposed finding is misleading and unreliable because Respondents have posed a hypothetical—a potential switch by Singlera to Thermo Fisher for its PanSeer MCED test—that evidence makes clear is impossible. Dr. Gao clearly testified that Singlera does not have a viable alternative to Illumina's NGS sequencer for its PanSeer test, (Gao (Singlera) Tr. 2901), and even described Illumina as the "800-pound gorilla" because it "control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies, too." (Gao (Singlera) Tr. 2951). Although Singlera evaluated the use of Thermo Fisher's NGS sequencers for use with its PanSeer test—when asked by Respondent's counsel if the PanSeer test is compatible with Thermo Fisher's NGS platforms, including its S5 sequencer, Dr. Gao merely said it was compatible "in theory." (Gao (Singlera) Tr. 2943). [redacted]

[redacted]

The proposed finding is also vague, confusing, incomplete, and misleading because Respondents have not defined or explained the terms "Thermo Fisher equipment," "bridging study," "revalidate," or "clinical trial work." These words are all material for understanding the proposed fact, and without defining each the proposed finding is incomplete and confusing. As a confusing, incomplete finding that is predicated on unrealistic hypothetical, this finding should be disregarded in its entirety. Therefore, this Court should disregard the proposed finding.

> 1894.1 Dr. Gao admitted that Singlera successfully raised $150 million, more money than Singlera had ever raised before, a few months after Illumina and GRAIL announced their merger. (Gao (Singlera) Tr. 2949–50.)

Response to Finding No. 1894.1

The proposed finding is vague, incomplete, misleading, and against the weight of the evidence. The proposed finding is vague because it is not clear whether Respondents are suggesting this is more money than Singlera had ever raised *in one round of fundraising* or in total fundraising to date. The proposed finding is incomplete and misleading because Respondent's counsel has omitted Dr. Gary Gao's additional testimony in which he elaborates that the fundraising will "always be larger and larger" and investors "thought they were worth

investing $150 million in . . . [b]ecause [Singlera] published [its] paper" and are "ahead of Illumina – Grail because of that paper." (Gao (Singlera) Tr. 2949–50.) Further, the proposed finding is misleading and against the weight of the evidence to the extent Respondents intend to suggest Illumina's acquisition of Grail has not hurt fundraising efforts by Grail's rivals. Dr. Gao in particular testified that he is concerned about the impact of Illumina's acquisition of Grail on Singlera's ability to raise money from investors, which, as he explained at trial, would be "very damaging" to the company and cause them to "lay off people, and then maybe narrow down things." [redacted] Therefore, this Court should disregard the proposed finding.

1895. Open Offer. Dr. Gao testified that he was "not even aware of the first open [...] offer until [his] lawyer told [him]", let alone the amended version. (Gao (Singlera) Tr. 2952 ("Q. And are you aware that that open offer was amended as of just last week to make certain improvements to it? A. Sir, to be frank, I am not even aware of the first open -- open offer until my lawyer told me, and I am not even aware of the one if you don't tell me a week ago.").)

Response to Finding No. 1895

The proposed finding is confusing, misleading, incomplete, and relies on testimony that Respondent's counsel requested the Court strike from the record. The proposed finding is confusing, misleading, and incomplete because Respondents have selectively quoted from Dr. Gao's testimony and removed the remaining portions of his testimony. In response to a question from Respondent's counsel question about his awareness of amendments to the open offer, Dr. Gao explained "Sir, to be frank, I am not even aware of the first open – open offer until my lawyer told me, and I am not even aware of the one if you don't tell me a week ago. You know, that issue is a little bit lack of sincerity from Illumina. I have been emailing them for agreement to send me a draft. They have open offer and never bother to contact me. I just want to complain here, okay?" (Gao (Singlera) Tr. 2952). Respondent's counsel moved to strike this answer, which the Court granted. (Gao (Singlera) Tr. 2952-53.) Despite its objections and the Court's ruling, Respondents now impermissibly seek to include a cherry-picked portion of Dr. Gao's

testimony as a fact and even cited the portion in its own brief. (*See* Resp's Brief at 275.). Therefore, this Court should disregard the proposed finding.

1896. Efficiencies. Complaint Counsel contends the Transaction will not generate efficiencies, but Dr. Gao admitted that Singlera's investors expressed concern that the Illumina-GRAIL merger will give GRAIL additional resources beyond what it has today and also strong financial backing from Illumina and give GRAIL the benefits of being part of a public company with unlimited resources, which will help GRAIL get the Galleri test approved sooner; in addition, having FDA experience in-house would save a company a significant amount of money. (Gao (Singlera) Tr. 2946–49.)

Response to Finding No. 1896

The proposed finding is vague, misleading, unsupported, unreliable, incomplete, and against the weight of the evidence. The proposed finding is vague, misleading, unreliable, and incomplete to the extent Respondents are using Dr. Gary Gao's testimony to establish a basis for their claimed efficiencies associated with this transaction. Respondents are relying on testimony from a third-party witness, Singlera Co-founder Dr. Gao, and what he heard *from unidentified "investors"* to establish that Illumina will provide "additional resources," "financial backing," and the "benefit of being part of a public company with unlimited resources" to Grail—none of which are defined in the alleged "fact." Although Dr. Gao can testify about what he's heard from investors about Singlera—a topic he is uniquely well positioned to provide reliable testimony about—Respondents are clearly using this testimony as hearsay to the extent they are offering it as support for their claimed efficiencies associated with this transaction. Respondents unquestionably carry the burden of substantiating the efficiencies they claim from this transaction. They are more than capable of producing evidence about the "additional resources," "strong financial backing," "benefits of being part of a public company with unlimited resources" about *their own company and transaction*. Their reliance on hearsay from a third-party witness only highlights their inability to substantiate these supposed efficiencies. Respondents have also mischaracterized Dr. Gao's testimony. Dr. Gao never testified that

investors told him Illumina will provide Grail with "additional resources," instead Respondent asked Dr. Gao if he *personally* believes Illumina could provide Grail with additional resources, which he responded by explaining in part this was "[t]rue with any other public company, like Roche." (Gao (Singlera) Tr. 2948).

Further, the proposed finding is also vague, misleading, unsupported, unreliable, and against the weight of the evidence to the extent Respondents are using Dr. Gao's testimony to establish Illumina can help Grail get its "Galleri test approved sooner," which is yet another term that Respondents have failed to define. Respondents have again mischaracterized Dr. Gao's testimony to suggest investors told Dr. Gao that Illumina could help Grail's Galleri get to market sooner—in actuality, Respondent's counsel again asked Dr. Gao if *he believed* Illumina's unidentified "resources" and "financial backing" would help Grail get the Galleri test "approved sooner." (Gao (Singlera) Tr. 2948). Again, this is a question that Dr. Gao clearly lacks adequate foundation to answer and even initially explained "I don't know how to answer you on this question." (Gao (Singlera) Tr. 2948). Finally, Respondents' use of Dr. Gao's testimony to establish "having FDA experience in-house would save a company a significant amount of money" is similarly vague and misleading to the extent they are implying anything about the supposed efficiencies associated with this transaction. Respondents have neither quantified a "significant amount of money" nor explained the relationship between the testimony of a third-party witness—in a question asked about *his own company*—and any cost savings associated with this transaction. (*See* Gao (Singlera) Tr. 2948). Respondents are unquestionably better positioned to support their alleged efficiencies with their own documents, which Respondents have failed to do. [redacted] Therefore, this Court should disregard the proposed finding.

1897. Bias. Complaint Counsel presented Dr. Gao as an unbiased witness, but Dr. Gao admitted that he spoke with FTC lawyers two separate times in 2020; in these conversations, the FTC lawyers went over the questions that they were going to ask Dr. Gao without anyone from GRAIL or Illumina present on those calls. (Gao (Singlera) Tr. 2904–06.)

Response to Finding No. 1897

The proposed finding is vague, misleading, unreliable, incomplete, and against the weight of the evidence, and thus should be disregarded. Respondent's counsel has suggested, without any support whatsoever, that Dr. Gary Gao is a biased witness merely because he testified that he spoke with FTC attorneys during the course of their investigation of Illumina's proposed acquisition of Grail. Respondents' counsel is surely aware of the FTC's obligation to protect the confidentiality of information collected from third parties during the course of an investigation as a law enforcement agency. Any suggestion that FTC lawyers are required, or even *permitted*, to include Respondents' counsel in communication with third-party witnesses during an investigation is outrageous. Dr. Gao also took oaths attesting to the truthfulness of his testimony before his Investigational Hearing on February 17, 2021, deposition on June 2, 2021, and trial testimony on September 13, 2021. In fact, Dr. Gao repeated several times during the portion of the trial testimony that Respondents cite that he didn't even remember what was discussed on his calls with the FTC lawyers. (Gao (Singlera) Tr. 2904-06). Any allegation that he was a "biased witness" is unquestionably against the weight of the evidence. Therefore, this Court should disregard the proposed finding.

11. **Jorge Velarde (Singular)**

a. Background

1898. Mr. Velarde is the Senior Vice President of corporate development and strategy at Singular Genomics. In his role, Mr. Velarde oversees all of the external collaborations, evaluations of potential licensing, partnering, and other commercial aspects of Singular Genomics' business. (Velarde (Singular) Tr. 4511–12.)

Response to Finding No. 1898

Complaint Counsel has no specific response to this proposed finding.

1899. Mr. Velarde has a degree in molecular biology from Loyola University, as well as a master's degree in business administration from UC Irvine. (Velarde (Singular) Tr. 4512.)

Response to Finding No. 1899

Complaint Counsel has no specific response to this proposed finding.

1900. After earning his MBA, Mr. Velarde was a research associate at Gen-Probe. Mr. Velarde climbed through the ranks of Gen-Probe to science-focused positions before joining Illumina in 2001. (Velarde (Singular) Tr. 4512–13.)

Response to Finding No. 1900

Complaint Counsel has no specific response to this proposed finding.

1901. Mr. Velarde worked at Illumina in corporate business development from 2001 to 2012 (Velarde (Singular) Tr. 4513.)

Response to Finding No. 1901

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1902. Upstream Market. While Complaint Counsel contends that there are no alternatives to Illumina in the upstream NGS market, Mr. Velarde confirmed that Singular currently have two NGS products in development, including the G4 NGS sequencer and the PX multiomics platform system; Singular is also developing core consumables for use with the G4 NGS instrument. (Velarde (Singular) Tr. 4513–14, 4521.)

Response to Finding No. 1902

This proposed finding is incomplete and misleading by implying Singular's NGS products in development would be viable alternatives for MCED test developers. [redacted]

[redacted] Lastly, to the extent the proposed finding implies that Singular's PX multiomics platform is a potential alternative to Illumina's NGS platform, Respondents have presented no evidence that a multiomics platform is a viable alternative to an NGS platform for MCED test developers. Therefore, this Court should disregard the proposed finding.

1903. Mr. Velarde confirmed that Singular is going to be commercially launching the G4 NGS sequencer at the end of 2021 and shipping the G4 NGS systems in the first half of 2022; Singular is currently on track to meet those target date to ship the G4 system in the first half of 2022. (Velarde (Singular) Tr. 4515–16, 4522.)

Response to Finding No. 1903

This proposed finding is incomplete to the extent it implies that Singular's impending commercial launch will be competitively meaningful in the near term. [redacted] Singular has also not generated any revenue and expects to incur significant losses in the near term (PX0068 at 23 (Singular Genomics S-1, May 2021)). In fact, Singular identified as a risk to investors that "we may require substantial additional funding" and substantial additional funding is not available Singular may be required to "delay, scale back, or cease our product development or commercialization activities." (PX0068 at 35 (Singular Genomics S-1, May 2021)). [redacted]

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

1904. [redacted] (Velarde (Singular) Tr. 4514, **4569–70**.)

Response to Finding No. 1904

[redacted]

[redacted]

1905. Mr. Velarde confirmed that Singular has developed the G4 systems and has completed beta testing for the G4 systems; Singular's beta testing occurred before its IPO by placing two different systems independently in Sanford Burnham and Fate Therapeutics, who successfully ran those systems with data published with Singular's IPO; Singular's beta test partners successfully used the sequencers themselves. (Velarde (Singular) Tr. 4516–17.)

Response to Finding No. 1905

[redacted]

[redacted]

1906. Mr. Velarde testified that Singular is conducting an early access program for the G4 systems by shipping the system to early access partners to generate data, technical notes, publications on the system to support the commercial launch at the end of 2021; Singular has completed one early access test with Beth Israel Deaconess Medical Center of Harvard Medical School, is in the process of another, and has just recently shipped the G4 system to a third early access partner; Singular expects to finish a number of early access tests before the end of 2021. (Velarde (Singular) Tr. 4516–19.)

Response to Finding No. 1906

This proposed finding is vague and misleading. Respondents do not provide any description of the applications of these early access customers. Nor do Respondents provide any context about the status of Singular's early access program. [redacted] By the time of Mr. Velarde's testimony at trial, still no more than three early access customers had been

recruited, meaning no MCED test developer had signed on to be an early access customer. (PX7117 (Velarde (Singular Genomics) Dep. at 4518). [redacted] By omitting this additional information this proposed finding is misleading by implying that customers have been eager to sign up for Singular's early access program. It is also misleading to the extent it implies that the information gathered by these early access customers, who are using Singular's G4 sequencer for applications other than MCED, would be remotely relevant to MCED test developers. Therefore, this Court should disregard the proposed finding.

1907. [redacted]

Response to Finding No. 1907

[redacted]

[redacted]

1908. Mr. Velarde confirmed that Singular is aggressively building out its sales and marketing force in preparation for the launch of the G4 system; Singular's sales and marketing force have a current head count of well over 200 right now. (Velarde (Singular) Tr. 4520–21.)

Response to Finding No. 1908

This proposed finding is vague. Respondents' do not define was it meant by

"aggressively building out" nor provide any comparator that places "well over 200" people in the sales force in context. Nor do Respondents provide any evidence of what types of customers and applications Singular's sales force anticipates targeting. [redacted] Therefore, this Court should disregard the proposed finding.

1909. [redacted] (Velarde (Singular) Tr. 4532, [redacted]

Response to Finding No. 1909

[redacted]

[redacted]

[redacted]

1910. [redacted] (Velarde (Singular) Tr. 4523–27, [redacted]

Response to Finding No. 1910

[redacted]

[redacted]

[redacted]

1911. Mr. Velarde confirmed that Singular designed its G4 NGS system in a way that would be the least disruptive to customers' workflow so Singular could offer the customers a system that would work for their needs; Singular's G4 NGS system was designed be compatible and work with a number of the library prep and bioinformatics workflows the customers have already developed for prior sequencing systems. (Velarde (Singular) Tr. 4532–34.)

Response to Finding No. 1911

This proposed finding is vague because Respondents do not describe what is meant by "least disruptive," or "customer workflow." It is also misleading and against the weight of the evidence. No MCED developer testified Singular has some magic shortcut to switching their sensitive assays that took years to optimize using Illumina's chemistry and adapter libraries. [redacted] Therefore, this Court should disregard the proposed finding.

1912. [redacted]

[redacted]

Response to Finding No. 1912

[redacted]

[redacted]

[redacted]

1913. Mr. Velarde testified that he does not think Illumina's reacquisition of GRAIL will have an effect on Singular's ability to innovate in the NGS space and Singular does not project that Illumina's reacquisition of GRAIL will slow down Singular's commercialization plans. (Velarde (Singular) Tr. 4534.)

Response to Finding No. 1913

This proposed finding is vague, confusing, and misleading. Respondents do not describe what is meant by "ability to innovate." This proposed finding is also confusing and misleading by omitting that MCED testing is only a portion of NGS market opportunity. MCED test is only one portion of NGS application in oncology. In turn, oncology represents only a portion of NGS applications. Singular's business plans are also not limited to NGS as they are also developing a multiomics platform. (PX7117 Velarde (Singular Genomics) Dep. at 16). Given this context is hardly surprising that Singular does not expect this proposed acquisition to generally impact their ability to innovate or commercialize. Therefore, this Court should disregard the proposed finding.

12. **William Cance (ACS)**

a. Background

1914. Dr. William Cance is the chief medical and scientific officer at the American Cancer Society (ACS) where he oversees the medical and scientific aspects of ACS's mission programs. (Cance (ACS) Tr. 591–92).

Response to Finding No. 1914

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1915. Background on Cancer Screening Guidelines. Dr. Cance testified that only five cancers are currently include in ACS's cancer screening guidelines, including breast, colorectal, lung, cervix, and prostate cancer: typically radiologic screening is used for breast cancer and for lung cancer; screening for cervical cancer is the Pap smear and also measuring human papilloma

virus DNA in the blood; colorectal cancer can be screened through looking at blood or DNA in the stool, or using colonoscopy; prostate cancer can be screened through elevation of PSA (prostate -specific antigen), which can also be elevated in benign disease, such as inflammation in the prostate. (Cance (ACS) Tr. 606).

Response to Finding No. 1915

Complaint Counsel has no specific response to this proposed finding.

1916. Dr. Cance testified that ACS recommends cancer screening tests for certain patients to detect cancer at an earlier stage where it can be intercepted, treated more successfully, and has a higher cure rate. (Cance (ACS) Tr. 606.)

Response to Finding No. 1916

Complaint Counsel has no specific response to this proposed finding.

1917. Dr. Cance confirmed that surgical operations on earlier stage cancer patients detected by screens have the benefits that the operation is more well-tolerated by the patient, it is frequently less invasive, the recovery is faster, and it has better cure rate. (Cance (ACS) Tr. 607–08.)

Response to Finding No. 1917

Complaint Counsel has no specific response to this proposed finding.

1918. Alleged Relevant Market. Complaint Counsel contends that several companies compete or will compete directly with GRAIL, but Dr. Cance admitted that GRAIL is further ahead in its development process than other companies that are developing purported MCED tests; he is not aware of any other purported MCED test that is commercially available today; GRAIL's Galleri test can detect 50 cancer types and he does not know of other companies having the same number of cancers detected as GRAIL. (Cance (ACS) Tr. 631–33.)

Response to Finding No. 1918

The proposed finding is misleading and incomplete, and it should be disregarded. It is misleading insofar as it suggests that Dr. Cance's testimony is probative of the bounds of the relevant market for MCED tests. Even if Grail is "further ahead in its development process" than other MCED test developers, that does not mean that Grail and other MCED test developers do not compete directly today or will not in the future.

The proposed finding is misleading and incomplete to the extent that it suggests that Dr.

Cance believes that Grail can screen for 50 early-stage cancers in an asymptomatic population. Dr. Cance was only asked whether Grail "detects" 50 cancers, which includes stage IV cancers and cancers found in symptomatic patients. (Cance (ACS) Tr. 632-633). Respondents' have used the same misleading characterization of Grail's ability to "detect" 50 cancers throughout the trial, when the evidence shows that Grail is only able to screen for seven early-stage cancers in an asymptomatic population. [redacted] Finally, the proposed finding is misleading because it mischaracterizes Dr. Cance's testimony on other MCED test developers. Dr. Cance was not testifying that he knows that other MCED test developers "detect" fewer cancers than Grail. Rather, he was testifying that he simply does not know the number of cancers that any other MCED test detects. (Cance (ACS) Tr. 633-635). Therefore, Respondents have taken Dr. Cance's testimony out of context.

1919. Cance Declaration. Complaint Counsel suggests that Dr. Cance's testimony supports their case, but Dr. Cance admitted that apart from the statement in the declaration that "ACS is an independent organization, and we do not take a position on the acquisition of GRAIL by Illumina," none of the statements in his declaration relate to Illumina's acquisition of GRAIL. (Cance (ACS) Tr. 638–40.)

Response to Finding No. 1919

The proposed finding is vague, misleading, and incomplete, and it should be disregarded. It is vague because it is unclear what Respondents mean by "relate to Illumina's acquisition of Grail." It is misleading and incomplete because the entirety of Dr. Cance's declaration relates to cancer treatments and MCED testing, which are relevant topics in this case even if Dr. Cance is not speaking directly about the Transaction. For example, Dr. Cance explained in his declaration that "[a]t this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variants, RNA variations, protein markers, or some other method for detecting cancer in the blood will prove most effective." (PX8398 (Cance (American Cancer Society) Decl. ¶ 11). This relates to the Transaction because it demonstrates that there is room for

innovation competition among MCED test developers to find the most effective scientific approach to MCED tests. Dr. Cance also emphasized that "multiple companies and institutions developing and improving [MCED] technology is very important." (PX7086 (Cance (American Cancer Society) Dep. at 100-101)).

1920. Dr. Cance testified that ACS takes no position on Illumina's acquisition of GRAIL: ACS takes no position on whether Illumina's acquisition of GRAIL will result in the loss of innovation in MCED tests, whether Illumina's acquisition of GRAIL will increase development costs for MCED tests, whether Illumina's acquisition of GRAIL will be harmful for patients, whether Illumina's acquisition of GRAIL will result in an injustice in health, whether Illumina's acquisition of GRAIL will increase the costs of healthcare, or whether Illumina's acquisition of GRAIL will reduce the supply of healthcare; ACS has not done any analysis to show whether Illumina's acquisition of GRAIL would result in any loss of innovation in MCED tests, would raise the cost of developing MCED tests, would harm patients, would result in an injustice in health, or would affect the costs or supply of healthcare. (Cance (ACS) Tr. 629–30.)

Response to Finding No. 1920

The proposed finding is misleading and incomplete, and it should be disregarded. It is misleading insofar as it suggests that Dr. Cance and ACS are not concerned about the Transaction. As Dr. Cance explained in his testimony, it is important that ACS be regarded as neutral toward all parties that can aid in the development of cancer treatments, and if ACS took an official position on the Transaction, it could negatively impact its mission. (Cance (ACS) Tr. 619-620). However, Dr. Cance emphasized that "multiple companies and institutions developing and improving [MCED] technology is very important." (PX7086 (Cance (American Cancer Society) Dep. at 100-101)). Specifically, Dr. Cance testified that innovation in the development of MCED tests is important because it is still unclear which test will ultimately be the most effective. (Cance (ACS) Tr. 621).

1921. Dr. Cance does not believe that any multicancer early detection tests should be stalled at its launch phase just so that other multicancer early detection tests can catch up sometime in the future and agrees that accelerating an early cancer detection test's ability to commercialize at scale is consistent with ACS's mission. (Cance (ACS) Tr. 631.)

Response to Finding No. 1921

The proposed finding is misleading and should be disregarded. Respondents make a straw man argument suggesting that Complaint Counsel is attempting to "stall" Galleri at its launch phase to allow other MCED tests to "catch up." This characterization of Complaint Counsel's intent is misguided. Rather, Complaint Counsel seeks to "level the playing field," as Illumina did when it spun off Grail in the first place. (*see* PX2624 (Illumina) at 009 (Email from D. Moriarty, Illumina, to J. Benson, Illumina, D. Baker, Illumina, Jan. 11, 2017, attaching "Grail Series B Overview," Jan. 5, 2017)). Moreover, the finding is misleading insofar as it suggests that the Transaction will allow Illumina to accelerate market access to Grail. [redacted]

[redacted]

13. **Andrew Felton (Thermo Fisher)**

a. Background

1922. Dr. Felton is the vice president of product management, platform research, and applied markets at Thermo Fisher Scientific (Thermo Fisher). He has been in this position for approximately seven years. (Felton (Thermo Fisher) Tr. 1978–79.).

Response to Finding No. 1922

Complaint Counsel has no specific response to this proposed finding.

b. Testimony

1923. Alleged Relevant Market. [redacted]

Response to Finding No. 1923

[redacted]

[redacted]

1924. Upstream Market and Alleged Foreclosure. [redacted]

Response to Finding No. 1924

[redacted]

[redacted]

[redacted]

1925. [redacted]

Response to Finding No. 1925

[redacted]

[redacted]

1926. [redacted]

Response to Finding No. 1926

[redacted]

[redacted]

1927. [redacted]

Response to Finding No. 1927

[redacted]

1928. [redacted]

[redacted]

Response to Finding No. 1928

[redacted]

1929. [redacted]

Response to Finding No. 1929

[redacted]

[redacted]

1930. [redacted]

Response to Finding No. 1930

[redacted]

[redacted]

1931. [redacted]

Response to Finding No. 1931

[redacted]

1932. [redacted]

Response to Finding No. 1932

[redacted]

[redacted]

1933. [redacted]

Response to Finding No. 1933

[redacted]

[redacted]

D. Respondents' Experts

1. Dennis Carlton

a. Background

1934. Dennis W. Carlton, Ph.D is the David McDaniel Keller Professor of Economics at The University of Chicago Booth School of Business. Dr. Carlton received his A.B. in Applied Mathematics and Economics from Harvard University and his M.S. in Operations Research and Ph.D. in Economics from the Massachusetts Institute of Technology. Dr. Carlton has served on the faculties of the Law School and the Department of Economics at The University of Chicago and the Department of Economics at the Massachusetts Institute of Technology. (RX3864 (Carlton Expert Report) ¶ 1); RX6000 (Carlton Trial Dep. at 5–7).)

Response to Finding No. 1934

The proposed finding is misleading and inaccurate to the extent it implies Dr. Carlton is an expert with respect to oncology, MCED tests, the FDA regulatory approval process for MCED tests, or the specific capabilities Illumina could contribute to accelerate Galleri, *See* (PX7134 (Carlton Dep. at 12-13); (Carlton (Illumina) Tr. 97, 102).

1935. Dr. Carlton specializes in the economics of industrial organization, which addresses topics in how firms compete, including the study of antitrust economics and of vertical integration. Dr. Carlton is the co- author of the book Modern Industrial Organization, a leading text in the field of industrial organization, and he has published over 100 articles in academic journals and books. In addition, Dr. Carlton serves as Co-Editor of the Journal of Law and

Economics, a leading journal that publishes research applying economic analysis to industrial organization and legal matters; serves on the Editorial Board of Competition Policy International, a journal devoted to competition policy; and serves on the Advisory Board of the Journal of Competition Law and Economics. Dr. Carlton has also served as an Associate Editor of the International Journal of Industrial Organization and Regional Science and Urban Studies, and on the Editorial Board of Intellectual Property Fraud Reporter. Dr. Carlton was the 2014 Distinguished Fellow of the Industrial Organization Society. (RX3864 (Carlton Expert Report) ¶ 2); RX6000 (Carlton Trial Dep. at 7–9).)

Response to Finding No. 1935

The proposed finding is misleading and inaccurate to the extent it implies Dr. Carlton is an expert with respect to oncology, MCED tests, the FDA regulatory approval process for MCED tests, or the specific capabilities Illumina could contribute to accelerate Galleri, *See* (PX7134 (Carlton Dep. at 12-13); (Carlton (Illumina) Tr. 97, 102).

1936. In addition to Dr. Carlton's academic experience, Dr. Carlton previously served as Deputy Assistant Attorney General for Economic Analysis, Antitrust Division, U.S. Department of Justice from October 2006 through January 2008. Dr. Carlton's responsibilities included supervising approximately 50 Ph.D. economists, helping formulate antitrust policy toward ongoing proposed mergers, analyzing general antitrust policies both horizontal and vertical, and communicating such policies to foreign and domestic agencies, as well as to practitioners. Dr. Carlton also served as a Commissioner of the Antitrust Modernization Commission, created by Congress to evaluate U.S. antitrust laws. Dr. Carlton has served as a consultant to the Department of Justice and Federal Trade Commission on the Horizontal Merger Guidelines, as a general consultant to the Department of Justice and Federal Trade Commission on antitrust matters, as a member of the American Bar Association advisory committee that advises the incoming President on antitrust policy, as an instructor to judges on antitrust economics at the Federal Judicial Center and as an advisor to the Bureau of the Census on the collection and interpretation of economic data. (RX3864 (Carlton Expert Report) ¶ 3); RX6000 (Carlton Trial Dep. at 10–11).)

Response to Finding No. 1936

The proposed finding is misleading and inaccurate to the extent it implies Dr. Carlton is an expert with respect to oncology, MCED tests, the FDA regulatory approval process for MCED tests, or the specific capabilities Illumina could contribute to accelerate Galleri, *See* (PX7134 (Carlton Dep. at 12-13); (Carlton (Illumina) Tr. 97, 102).

1937. Dr. Carlton also is a Senior Managing Director of Compass Lexecon, a consulting firm that specializes in the application of economics to legal and regulatory issues and for which

he served as President (of Lexecon) for several years. Dr. Carlton has provided expert testimony before various U.S., state and federal courts, the U.S. Congress, a variety of state and federal regulatory agencies and foreign tribunals. Dr. Carlton has consulted to or testified for companies that were involved in vertical transactions, including offering economic expert testimony on behalf of AT&T in its recent acquisition of Time Warner. Dr. Carlton's curriculum vitae and a list of his testifying experience over the last four years is provided in Exhibit 1. Compass Lexecon bills for Dr. Carlton's time on this matter at his customary hourly rate, which is currently $1,800 per hour. Neither Dr. Carlton's compensation nor that of Compass Lexecon is dependent on the outcome of this proceeding. (RX3864 (Carlton Expert Report) ¶ 4); RX6000 (Carlton Trial Dep. at 12–13).)

Response to Finding No. 1937

The proposed finding is misleading and inaccurate to the extent it implies Dr. Carlton is an expert with respect to oncology, MCED tests, the FDA regulatory approval process for MCED tests, or the specific capabilities Illumina could contribute to accelerate Galleri, *See* (PX7134 (Carlton Dep. at 12-13); (Carlton (Illumina) Tr. 97, 102).

The proposed finding is incomplete and misleading as the phrase "AT&T in its recent acquisition" omits that AT&T has already had to unwind its acquisition of Time Warner, in part due to the failure to achieve claimed efficiencies. *See* (PX7134 (Carlton Dep. at 42-43, 57)).

b. Summary of Opinions

1938. Dr. Carlton testified that Illumina's acquisition of GRAIL is unlikely to lead to any adverse competitive effects as alleged by Complaint Counsel and is likely to generate efficiency benefits for customers of GRAIL and ultimately for patients. (RX3864 (Carlton Expert Report) ¶ 13; RX6000 (Carlton Trial Dep. at 15).) Specifically, Dr. Carlton concluded the following:

Response to Finding No. 1938

The proposed finding is vague, unsupported, incomplete, and contradicted by the weight of the evidence. First, the proposed finding is vague, unsupported and incomplete because it refers to "efficiency benefits" without identifying any specific efficiencies. It also refers to "Dr. Carlton concluded the following:" but abruptly stops and does not specify what Dr. Carlton specifically concluded.

Second, the portion of the proposed finding that "Illumina's acquisition of GRAIL is unlikely to lead to any adverse competitive effects" is unsupported and contradicted by the weight of the evidence. The cited evidence for the proposed finding is *only* testimony from Respondents' economic expert, Dr. Carlton. In contrast, the weight of the record evidence, including testimony from MCED developers, other market participants, and ordinary course business documents clearly demonstrates that the Acquisition has a reasonable probability of substantially lessening competition. *See* Complaint Counsel's Post-Trial Brief at Section II.E; Complaint Counsel's Post-Trial Reply Brief at Section III. Therefore, the proposed finding should be disregarded.

1939. Fully accounting for the effects of a vertical transaction requires an economic vertical model that simultaneously accounts for the countervailing forces of raising rivals' costs ("RRC") and the elimination of double marginalization ("EDM") and other efficiencies (which interact with each other in complicated ways) as well as the impact of constraints, including the Open Offer, reputation constraints, and the ability of MCED test providers to take steps to reduce their reliance on Illumina. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 24–26).)

Response to Finding No. 1939

The proposed finding is vague, unsupported, incomplete, and contradicted by the weight of the evidence. First, the term "economic vertical model" is vague because there is no description of such a model in either the proposed finding or the underlying cited testimony. Second, the proposed finding is unsupported as there is no cited support for the claim that "[f]ully accounting for the effects of a vertical transaction requires an economic vertical model" apart from the report and testimony of Respondents' economic expert.

Third, the proposed finding is also incomplete because it purports to describe some aspects of a "economic vertical model" but does not make clear whether it is describing everything that must be included in such a model. Dr. Carlton made clear that he did not produce a "full vertical model" to analyze the transaction, so nothing that he produced can be

used as a basis of comparison. (RX6000 (Carlton Trial Dep. at 136-137) ("I want to be clear. I – I do not have a full vertical model.")). The finding is also unsupported by economic theory because Dr. Carlton does not cite to anything in support of his assertion that a "economic vertical model" is required in order to conduct a complete analysis of a vertical merger. To the extent that Dr. Carlton is claiming that the legal standard for proving anticompetitive harm in a vertical merger requires such a model, he is not qualified to make such a claim.

Finally, the proposed finding is also incorrect, unsupported, and misleading to the extent it suggests that an empirical model is the only way to assess the likely competitive effects of a proposed vertical merger. [redacted] The weight of the evidence—i.e., not just Respondents' expert testimony, but *all* of the testimony in this matter, including testimony from MCED developers, other market participants, and Respondents' ordinary course documents—

clearly demonstrates that the Acquisition has a reasonable probability of substantially lessening competition. *See* Complaint Counsel's Post-Trial Brief at Section II.E; Complaint Counsel's Post-Trial Reply Brief at Section III. Therefore, the proposed finding should be disregarded.

> 1939.1 A fully specified model must take into account many economic factors, including the amount of diversion, margins and costs, and the specification of the type of competition that determines pre- and post-merger prices and investments. Neither Complaint Counsel nor Dr. Scott Morton have offered such a model, relying instead on assumptions, including that there are no merger-specific efficiencies that cannot be achieved by contract and that the Open Offer provides no protection to customers, as well as assumptions about future rivals. Complaint Counsel's and Dr. Scott Morton's assertions that Illumina will have an incentive and ability to harm competition as a result of this transaction are therefore highly speculative. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 24–26).)

Response to Finding No. 1939.1

The proposed finding is vague, unsupported, incomplete, and contradicted by the weight of the evidence. First, the term "fully specified model" is vague because there is no description of such a model in either the proposed finding or the underlying cited testimony. Second, the proposed finding is unsupported as there is no cited support for the claim that "a fully specified model must take into account many economic factors" apart from the report and testimony of Respondents' economic expert.

Third, the proposed finding is also incomplete because it purports to describe some aspects of a "fully specified economic model" but does not make clear whether it is describing everything that must be included in such a model. Dr. Carlton made clear that he did not produce a "full vertical model" to analyze the transaction, so nothing that he produced can be used as a basis of comparison. (RX6000 (Carlton Trial Dep. at 136-137) ("I want to be clear. I – I do not have a full vertical model.")). The finding is also unsupported by economic theory because Dr. Carlton does not cite to anything in support of his assertion that a "fully specified economic model" is required in order to conduct a complete analysis of a vertical merger. To the

extent that Dr. Carlton is claiming that the legal standard for proving anticompetitive harm in a vertical merger requires such a model, he is not qualified to make such a claim.

[redacted]

[redacted] The weight of the evidence—i.e., not just Respondents' expert testimony, but *all* of the testimony in this matter, including testimony from MCED developers, other market participants, and Respondents' ordinary course documents—clearly demonstrates that the Acquisition has a reasonable probability of substantially lessening competition. *See* [redacted] Therefore, the proposed finding should be disregarded.

1940. [redacted]

[redacted]

Response to Finding No. 1940

[redacted]

[redacted]

1941. Complaint Counsel's alleged market for MCED tests is not defined based on any empirical examination of demand for such a product (because Galleri was only introduced in April 2021, and none of the rivals identified by Complaint Counsel or by Dr. Scott Morton (or any other test developers as far as Dr. Carlton is aware) have a product in their alleged market today), but instead on speculative characteristics of potential future products, some of which are not yet even in development. Neither Dr. Scott Morton (as she acknowledges) nor Complaint Counsel can offer reliable estimates of shares and diversion ratios of sales from GRAIL and its rivals. Without these, it is not possible for Dr. Scott Morton to analyze the overall effect of a vertical merger where there are efficiencies that need to be balanced against any alleged incentive to RRC, and where post-merger constraints exist. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

Response to Finding No. 1941

[redacted]

[redacted]

[redacted]

1942. Complaint Counsel's first theory of harm is that Illumina will raise GRAIL's rivals' costs by increasing the prices of Illumina-supplied inputs. Because of the Open Offer, Complaint Counsel has not shown that Illumina has the ability to raise costs. Complaint Counsel's theory requires that rivals' costs could be significantly raised by Illumina increasing prices on the inputs it will supply. Such price increases would violate Illumina's contractual commitment not to raise the prices as specified in the Open Offer and to reduce sequencing costs 43 percent by 2025 as specified in the Open Offer. These contractual restrictions indicate that Illumina could not raise rivals' costs, let alone raise them by an amount sufficient to drive up the prices GRAIL's rivals charge for their tests to create meaningful diversions to GRAIL. Moreover, even absent the contractual commitment, Illumina raising input prices to harm GRAIL's competition is unlikely. Current estimates show that Illumina input costs could comprise less than four percent of an equally efficient GRAIL rival's revenues within five years of that rival launching its test. Given this, any attempted price increase would likely have to be very significant to cause substantial harm and could damage Illumina's reputation and dampen investment in the development of other downstream products on the Illumina sequencing platform. These reputational effects should mitigate or eliminate Complaint Counsel's concerns about RRC. Additionally, to the extent that, as Illumina expects, there will be greater upstream competition in the coming years (including following the expiration of its key sequencing patents in 2023), that further constrains Illumina's incentive to raise price. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

Response to Finding No. 1942

[redacted]

[redacted]

[redacted]

1943. Complaint Counsel's second theory of harm is that Illumina will fail to provide information, access, and assistance to GRAIL's rivals. And, as with RRC, this theory ignores that GRAIL's rivals will be protected from this potential harm by contract through the Open Offer. The contractual protections in the Open Offer provide for GRAIL's rivals to have access to Illumina's future sequencing platforms and support services on the same basis that such access is provided to GRAIL, and that Illumina will continue to offer assistance with downstream rivals' pursuit of cancer screening tests (including IVD Test Kits in the event a rival decides to pursue such a model—though such a model is not anticipated in the U.S. in the foreseeable future), to the extent that the rivals' require that assistance in securing FDA approval for such tests, consistent with Illumina's pre-merger practices. (PX0064 (Illumina) § 4, 6). The inability to write a complete contingent contract that anticipates every possible state of the world where a rival might ask Illumina for help—and where Illumina would have provided such help in the but-for world—does not mean that the contractual protections offered by Illumina are meaningless, which is apparently Complaint Counsel's position and is reflected in Dr. Scott Morton's analysis, which assumes that the Open Offer has no constraining effects on Illumina's actions whatsoever. Why Complaint Counsel believes that the Open Offer's method of handling unforeseen contingencies, via terms that are favorable to customers and subject to arbitration, favors Illumina is unclear. This method of dispute resolution allows the efficiencies of the transaction to be achieved while eliminating Complaint Counsel's concern of significant harm. In addition, Complaint Counsel's theory ignores that Illumina will be constrained by the prospect that attempts to raise rivals' costs would damage Illumina's reputation and cause downstream firms to reduce investments in new uses for Illumina's sequencing products, as well as lose upstream sales to new entrants and expansion by existing rivals. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

Response to Finding No. 1943

[redacted]

[redacted]

1944. EDM and other efficiencies projected by Illumina are merger-specific, will be passed through to downstream customers, and are likely to be of significant magnitude. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

Response to Finding No. 1944

[redacted]

[redacted]

1945. [redacted]

[redacted]

Response to Finding No. 1945

[redacted]

[redacted]

[redacted]

1946. The acquisition will likely result in merger-specific R&D efficiencies. The existence of such efficiencies would not be surprising, as vertical integration is common in industries in which R&D is important. Such vertical integration occurs because the efficiencies that come from combining two companies' complementary R&D efforts often cannot be achieved by contract. Post-merger collaboration between GRAIL and Illumina means there will be a higher probability of breakthrough discoveries. That collaboration does not occur prior to the acquisition because of the well-known difficulty of collaboration by contract when proprietary IP (e.g., GRAIL's data and algorithm), and the inherent reservations about the disclosure of such confidential information, is involved. It is exactly such collaboration in a vertical setting (after Illumina's acquisition of Verinata) that led to discoveries that led to the formation of GRAIL. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 61–63).)

Response to Finding No. 1946

The proposed finding is unsupported and contradicted by the weight of the evidence. First, this Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46.

Second, the claim that the merger will result in merger-specific R&D efficiencies is contradicted by the weight of the evidence. The weight of the evidence shows that many of the claimed R&D "breakthroughs" have already been discovered by Grail, and simply require investment to materialize. For example, Respondents claim the Acquisition will lead to insights allowing Grail's technology to apply to other diseases, including "fatty liver disease,"

Respondents' Post-Trial Brief at 203, but Respondents' executives admitted at trial that Grail *already* has developed evidence that its technology can be applied to other technologies—including "fatty liver disease." (CCFF ¶ 5753); (Aravanis (Illumina) Tr. 1955). In fact, Grail already is [redacted] (CCFF ¶¶ 5748-50). Similarly, the proposed finding is contradicted by the weight of the evidence, which shows that Illumina lacks any unique assets or experience that position it as the only company that could help Grail achieve such R&D advances. With respect to financing, Grail would have been able to attain funding through less anticompetitive means than the Acquisition. For example, prior to the Acquisition, [redacted] (CCFF ¶¶ 5864, 5904). Grail stated in its Amended Form S-1 its intention to use these proceeds "for current and future product development[.]" (CCFF ¶ 5895). [redacted] (CCFF ¶¶ 5915-5952), and investors remained interested in a Grail IPO (and Grail remained ready) even after the Illumina acquisition was announced, (CCFF ¶¶ 5959-5962). Besides an IPO, Grail [redacted] (CCFF ¶¶ 5963-5966). In fact, one Grail ordinary course strategic document noted that [redacted]

[redacted] *See also* Complaint Counsel's Post-Trial Reply Brief at Section V.C.2.

Additionally, the claim that "[i]t is exactly such collaboration in a vertical setting (after Illumina's acquisition of Verinata) that led to discoveries that led to the formation of GRAIL" is incorrect and contradicted by the weight of the evidence. Record evidence, including Illumina's ordinary course documents, directly contradict the claims that the Verinata transaction was the source of the discovery leading to Galleri. Specifically, Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings of National Academy of Science journal in 2008 presenting research on the detection of fetus chromosome trisomy using cfDNA. (CCFF ¶ 354). Dr. Gao used the research from his 2008 paper with Dr. Dennis Lo to begin research on the use of cfDNA for cancer screening. (CCFF ¶ 354). As early as 2009, Dr. Gao published a paper on DNA methylation for use in applications such as cancer detection in 2009 with Singlera co-founder Professor Kun Zhang of the University of California San Diego. (CCFF ¶ 355). By 2012, Dr. Lo's research caught the attention of Illumina. In August 2012, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina's SVP of Corporate and Venture Development, Nicholas Naclerio, to alert Naclerio of research by Dr. Dennis Lo. (CCFF ¶ 369). Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [noninvasive prenatal testing]," (CCFF ¶ 371), and suggested that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (CCFF ¶ 372). Just one month later, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought to review Dr. Lo's "filed patent applications." (CCFF ¶ 373). In notes from the call, Illumina's attendees wrote the question, "How will a clinician use this type

of data?" (CCFF ¶ 373). Responses to the question included "*Blood biopsy – non-invasive screening" and "Potential for detecting cancer prior to actual detection of a primary tumor*." (CCFF ¶ 373 (emphasis added)).

Finally, the proposed finding is only supported by the testimony of Respondents' expert, and is not supported by any testimony by fact witnesses or ordinary course documents. Therefore, the proposed finding should be disregarded.

2. **Richard Cote**

a. Background

1947. Dr. Richard J. Cote is the Edward Mallinckrodt Professor and Chair at the Department of Pathology and Immunology, Washington University School of Medicine at St. Louis, Missouri. He is also the Pathologist-in-Chief at Barnes-Jewish Hospital of St. Louis, Missouri. (RX3869 (Cote Expert Report) ¶ 1); Cote Tr. 3717.)

Response to Finding No. 1947

Complaint Counsel has no specific response to this proposed finding.

1948. Dr. Cote is a board-certified pathologist, serving over 25 years in senior academic, consultative, director and clinical roles with leading universities, hospitals and healthcare enterprises. (RX3869 (Cote Expert Report) ¶ 2); Cote Tr. 3717–19.)

Response to Finding No. 1948

Complaint Counsel has no specific response to this proposed finding.

1949. Before joining Washington University in 2019, Dr. Cote was the Joseph R. Coulter Jr. Chair of the Department of Pathology, Professor of Biochemistry and Molecular Biology, and Founding Director of the Dr. John T. Macdonald Foundation Biomedical Nanotechnology Institute at the University of Miami Miller School of Medicine at Miami, Florida, since 2009. He was also the Chief of Pathology at the Jackson Memorial Hospital and the Director of the Genitourinary Cancer Program at the University of Miami Sylvester Comprehensive Cancer Center at Miami, Florida. (RX3869 (Cote Expert Report) ¶ 3); Cote Tr. 3717–18.)

Response to Finding No. 1949

Complaint Counsel has no specific response to this proposed finding.

1950. Prior to 2009, Dr. Cote was Professor at the Departments of Pathology and Urology at the University of Southern California ("USC") Keck School of Medicine; Director of the Genitourinary Cancer Program and Attending Pathologist at USC Norris Comprehensive Cancer Center; Director of the Laboratory of Immunology and Molecular Pathology in Los Angeles, California; and Director of the USC Biomedical Nanoscience Initiative at the USC Keck School of Medicine. He was also a Clinical Instructor at the Department of Pathology at the Cornell University Medical College in New York City before joining USC in 1990. (RX3869 (Cote Expert Report) ¶ 4); Cote Tr. 3718.)

Response to Finding No. 1950

Complaint Counsel has no specific response to this proposed finding.

1951. Dr. Cote received a B.A. in Chemistry and B.S. in Biology, both with honors, at the University of California at Irvine, and an M.D. from the University of Chicago Pritzker School of Medicine in Chicago, Illinois. He completed a surgical internship at the University of Michigan at Ann Arbor, Michigan, and a residency in pathology at the New York Hospital of Cornell University Medical College, a clinical fellowship in pathology and research fellowship in Human Tumor Immunology at Memorial Sloan-Kettering Cancer Center, and a fellowship in Molecular Pathology at the New York University School of Medicine in New York City. (RX3869 (Cote Expert Report) ¶ 5); Cote Tr. 3717–18.)

Response to Finding No. 1951

Complaint Counsel has no specific response to this proposed finding.

1952. Dr. Cote's research is focused on the elucidation of cellular and molecular pathways of tumor progression and response to therapy. He has special interests in micro-metastases and circulating tumor cell detection, characterization, and pathology of breast and genitourinary tumors. He has led three of the largest clinical trials in breast, lung and bladder cancer, all based on discoveries from his research. (RX3869 (Cote Expert Report) ¶ 6); Cote Tr. 3719, 3724.)

Response to Finding No. 1952

Complaint Counsel objects to the proposed finding because it is misleading to the extent it suggests that any purported experience with "circulating tumor ***cell*** detection" has anything whatsoever to do with the detection of circulating tumor ***DNA*** for the purpose of MCED testing.

Complaint Counsel has no other specific response to this proposed finding.

1953. Dr. Cote is the author of over 300 publications, and he participates on numerous scientific advisory boards for both academic and industry related institutions. He is a frequent lecturer and the co-author of the standard textbooks "Immunomicroscopy: A Diagnostic Tool for the Surgical Pathologist" (now in its third edition) and "Modern Surgical Pathology" (now in its

second edition). He also serves as a member and advisor to a large number of national and international study groups, cancer programs and societies, including the National Cancer Institute. (RX3869 (Cote Expert Report) ¶ 7).)

Response to Finding No. 1953

Complaint Counsel has no specific response to this proposed finding.

1954. Dr. Cote's laboratory is also focused on technology development, where he and his colleagues have developed immunohistochemical and molecular methods, such as antigen retrieval. With colleagues at the University of Miami, USC, California Institute of Technology (Caltech), and University of California at Berkeley, Dr. Cote has developed nanoscale technologies for cancer diagnostic applications, including bionanosensors for the detection of serum tumor markers, and technologies for the capture, characterization and propagation of circulating tumor cell. Through these efforts, he established the Biomedical Nanoscience Program at USC and the Dr. John T. Macdonald Biomedical Nanotechnology Institute at the University of Miami (BioNIUM) for the development of novel diagnostic platforms and targeted therapeutics. (RX3869 (Cote Expert Report) ¶ 8.)

Response to Finding No. 1954

Complaint Counsel objects to the proposed finding because it is misleading to the extent it suggests that any purported experience with "circulating tumor ***cell*** detection" has anything whatsoever to do with the detection of circulating tumor ***DNA*** for the purpose of MCED testing.

Complaint Counsel has no other specific response to this proposed finding.

1955. Dr. Cote also founded several technology companies, including several that focused on cancer testing and cancer analysis. These companies include IMPATH, Clarient, Filtini, Sensitini and Circulogix. IMPATH was one of the first companies to bring esoteric testing for cancer analysis to the market. Dr. Cote founded IMPATH in 1988 to conduct cancer testing and analysis on a contract basis for smaller hospitals that did not perform cancer testing in their own laboratories. It underwent IPO in 1996 and was acquired in 2004 by Genzyme, now a subsidiary of Sanofi. (RX3869 (Cote Expert Report) ¶ 9); Cote Tr. 3724.)

Response to Finding No. 1956

Complaint Counsel objects to the proposed finding because it is vague, as it is unclear what "founded" means, exactly what "cancer analysis" refers to, or what "esoteric testing for cancer analysis" means. Therefore, this Court should disregard the proposed finding.

1956. Dr. Cote also helped to start a cellular image analysis company, ChromaVision Medical Systems, Inc. ChromaVision developed an Automated Cellular Imaging System

(ACIS®) designed to assist physicians by detecting, counting and classifying cells of clinical interest based on color, size and shape. It underwent IPO in 1997 and Dr. Cote served on ChromaVision's Scientific Advisory Board between 1997 and 2000. In 2003, he helped direct a re-engineering of the company and changed its name to Clarient in 2005. Since 2005, Clarient's revenues had grown at a 68 percent compounded annual growth rate until it was acquired by GE Healthcare in 2010. (RX3869 (Cote Expert Report) ¶ 10.)

Response to Finding No. 1956

Complaint Counsel has no specific response to this proposed finding.

1957. Dr. Cote founded Filtini in 2008 to develop membrane microfilters to trapping circulating tumor cells, which help in the detection of recurrence of bladder cancer. He founded Sensitini in 2009 to use monoclonal antibodies to detect tumor-specific antigens and trace amounts of toxin in the blood. He also co-founded Circulogix in 2014 to develop the technology to enrich and capture circulating tumor cells and circulating Cancer Associated Fibroblasts ("cCAF") from body fluid samples (*i.e.*, blood, urine, ascites) for cancer characterization using immunofluorescence, immunochemistry, fluorescence in situ hybridization ("FISH"), RNA in situ hybridization ("RNA ISH"), next-generation sequencing ("NGS"), and tissue culture. (RX3869 (Cote Expert Report) ¶ 11).

Response to Finding No. 1957

Complaint Counsel has no specific response to this proposed finding.

1958. Dr. Cote holds numerous patents for cancer related and nanoscale technologies relating to the research conducted in his laboratories and companies. He was recently elected in to the National Academy of Inventors based on the impact of his inventions. (RX3869 (Cote Expert Report) ¶ 12); Cote Tr. 3721.)

Response to Finding No. 1958

Complaint Counsel has no specific response to this proposed finding.

b. Summary of Opinions

1959. Market Definition. Dr. Scott Morton's analysis of test developers who are currently pursuing cancer screening tests capable of screening for more than one type of cancer (which she refers to as the "multi-cancer early detection" market) is flawed. (RX3869 (Cote Expert Report) ¶ 15).

Response to Finding No. 1959

Complaint Counsel objects to the proposed finding because it is vague, Dr. Cote is not qualified to provide expert opinion testimony on this subject, and Dr. Cote is not a credible

witness.

The proposed finding is vague because it does not specify what analysis of Dr. Scott Morton's it is referring to and how that analysis is purportedly flawed.

Dr. Cote is not qualified to provide expert opinion testimony about relevant market definition or whether other MCED tests will compete in the same market with the Galleri test, so his opinion is not entitled to any weight. Dr. Cote is not an economist. (Cote Tr. 3988). Dr. Cote does not have an MBA. (Cote Tr. 3964.) Dr. Cote has never been retained as an expert in an antitrust case and is not "very knowledgeable about antitrust." (Cote Tr. 3961, 89). Dr. Cote did not apply a hypothetical monopolist test in his report. (Cote Tr. 3989). As a clinical pathologist, it is not part of Dr. Cote's job to "order early cancer screening tests for asymptomatic patients." (Cote Tr. 3978-79). Dr. Cote is not qualified to provide expert opinion testimony [redacted]

Dr. Cote's opinion about which MCED tests will compete in the same relevant market with the Galleri test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Dr. Cote is not qualified to opine on the appropriate legal or economic standard for defining a relevant antitrust product market. But he did articulate the standard that he employed for his analysis. [redacted]

[redacted] This is simply not a reliable or useful analysis, and this Court should not accord Dr. Cote's opinion any weight.

Dr. Cote is not a credible witness on this or any subject, so his opinion is not entitled to any weight. Dr. Cote offered opinion testimony in this matter that spans multiple disparate subjects not plausibly within the expertise of any single witness and certainly exceeding his expertise:

- the "development and commercialization timeline of certain next-generation sequencers";
- "which next-generation sequencing platforms are viable for multicancer screening tests";
- the "process and timeline for developing a multicancer early detection test"; and
- "whether other multicancer early detection tests will compete with the Galleri test."

(Cote Tr. 3961-62). Respondents are simply attempting to use paid opinion testimony from Dr. Cote to plug any and every hole in their case, in place of reliable evidence. Respondents are paying Dr. Cote "$900 per hour for [his] work on this matter." (Cote Tr. 3959). Dr. Cote estimated that as of September 21, 2021, the date of his trial testimony, he had worked "at least several hundred hours" on this matter. (Cote Tr. 3959). Dr. Cote refused to confirm whether he had been paid over $270,000 for his work on this matter and was unable to do the math to calculate estimate how much he had been paid. (Cote Tr. 3959-60). In addition to the breadth of subjects over which Dr. Cote claims expertise in the present matter, he has on numerous occasions offered opinion testimony in medical malpractice cases. (Cote Tr. 3960). Dr. Cote was unable to provide his best estimate of the number of medical malpractice cases in which he has been retained. (Cote Tr. 3960-61). Dr. Cote, however, has not offered expert opinion in any antitrust case or any other case involving either next-generation sequencers or MCED tests. (Cote Tr. 3961, 89).

Dr. Cote is also not credible because his trial testimony contained unsupported claims about his experience related to MCED test development that exceed the information disclosed in his report. [redacted] At trial, Dr. Cote could not confirm whether the Curriculum Vitae in his expert report contained a complete list of each commercial corporation that he has done work for in a full-time capacity, each company that he has consulted for or served as a scientific advisor, or each company at which he served on the board of directors (Cote Tr. 3973-74). At trial, Dr. Cote claimed that he has served on the board of directors of at

least three companies that are developing a multicancer screening test—GoPath, IMPATH, and Flagship. (Cote Tr. 3976 ("Q. [H]ave you served on the board of directors of any company that's developing a multicancer screening test? A. Yes. Q. Which companies? A. GoPath, Impath, let's see, Flagship.")). None of these claims about his experience holds up, severely damaging Dr. Cote's credibility. [redacted]

Dr. Cote is also not credible because he has been wrong in the past about BGI entering the U.S. NGS market. [redacted] Around 2015-2016, University of Miami began offering an NGS-based cancer therapy assessment panel. (Cote Tr. 3979-80). Dr. Cote and the University of Miami considered acquiring a BGI sequencer in order to run that assay onsite. (Cote Tr. 3980). Dr. Cote signed a letter of intent with BGI related to acquiring an instrument for the purpose of running the assay. (Cote Tr. 3980). Dr. Cote was hoping to be at the vanguard of having the first clinical offering using BGI technology in the United States. (Cote Tr. 3981). At the time, Dr. Cote evaluated the BGI platform for the cancer

therapy selection panel assay, he expected that BGI's technology would be available in the United States within six months. (Cote Tr. 3981). However, Dr. Cote's assessment was wrong—BGI's technology did not become commercially available in the United States within six months as Dr. Cote had expected. (Cote Tr. 3981). The reason BGI's technology did not become commercially available in the United States within six months as Dr. Cote had expected is that Illumina obtained an injunction against BGI. (Cote Tr. 3981-82). Instead, the cancer therapy assessment panel was brought online at University of Miami on an Illumina platform. (Cote Tr. 3982).

Dr. Cote is not credible with respect to analyzing the prospect of BGI entering the U.S. market going forward either, as he remains inexplicably unaware of critical relevant facts. [redacted]

Beyond that, Dr. Cote did not do any work to determine whether Illumina has any additional patent infringement claims pending against BGI (Cote Tr. 3985) and is not even aware that Illumina is already seeking additional injunctive relief against BGI in federal court in the District of Delaware in the suit captioned *Complete Genomics, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.), [redacted]

Dr. Cote admitted he has no knowledge of this lawsuit, Illumina's counterclaims in this lawsuit, the patents at issue in this lawsuit, or the expiration dates of those patents. (Cote Tr. 3986-87). He has not analyzed or reviewed any analysis of whether BGI's sequencers infringe the patents

Illumina is asserting in this suit. (Cote Tr. 1987). Nor does he have any knowledge of Illumina's legal strategy with respect to BGI or BGI's legal or business strategy with respect to Illumina. (Cote Tr. 3987-88). Dr. Cote's lack of any knowledge about these patent claims Illumina is *already* asserting against BGI did not stop him from [redacted] Dr. Cote's willingness to dispense purported expert opinion without foundation or diligence should cause this Court to discount his opinion testimony generally, not just on this subject. This Court should disregard the proposed finding.

1960. It is undisputed that a purported "multi-cancer screening market" does not exist today. Only one multi-cancer screening test (GRAIL's Galleri test) is currently commercially available and only as a laboratory developed test ("LDT"). Therefore, it is speculative to predict what the cancer screening market will look like in the future, and how cancer screening tests currently in development (and other cancer screening tests that are yet to be developed) will compete with each other, if at all. (RX3869 (Cote Expert Report) ¶15); Cote Tr. 3727.)

Response to Finding No. 1960

Complaint Counsel objects to the proposed finding because it is incorrect and misleading, against the weight of the evidence, improperly cites expert testimony, Dr. Cote is not a credible witness, Dr. Cote is not qualified to provide expert opinion testimony on these subjects, and Dr. Cote's opinion is unreliable.

The proposed finding is incorrect and misleading because it claims it is "undisputed" that a multi-cancer screening market does not exist today. Complaint Counsel alleged and proved the existence of a relevant product market [redacted]

The proposed finding based on Dr. Cote's paid expert opinion is against the weight of the evidence because it is contrary to the fact witnesses that are well positioned to testify as to whether a MCED market exists. In fact, the evidence shows that the Galleri test is currently being sold and at the time of trial Grail [redacted] As Kevin Conroy, CEO of Exact Sciences, explained, "I believe there is a nascent market that has begun once Galleri became available." (Tr. 1738).

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source of evidence supporting the fact that "[o]nly one multi-cancer screening test (GRAIL's Galleri test) is currently commercially available and only as a laboratory developed test," in contravention of this Court's Order. This Court should disregard this evidence.

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

Dr. Cote is not qualified to provide expert opinion testimony about [redacted]

[redacted]

Dr. Cote is also not qualified to provide expert opinion testimony about the process and timeline for developing a multicancer screening test. For example, Dr. Cote testified that "the development of a cancer screening test using modern technologies, such as NGS technology, is a very difficult, time-consuming, extremely expensive and risky process, and this is true for even a single cancer screening test but is particularly true in the case of a multicancer screening test." (Cote Tr. 3783). [redacted] Dr. Cote has never done any full-time work for any company developing an MCED test. (Cote, Tr. 3974-75). At trial, Dr. Cote claimed that he has served on the board of directors of at least three companies that are developing a multicancer screening test—GoPath, IMPATH, and Flagship. (Cote, Tr. 3976). But this claimed experience does not withstand scrutiny. Regarding GoPath, [redacted]

[redacted] Having failed to properly disclose his affiliation with GoPath, as required by the Scheduling Order (*see* Scheduling Order at 8 ("[e]ach expert report shall include … the qualifications of the expert")), this Court should reject Dr. Cote's claim of possessing any relevant experience based on GoPath. Regarding IMPATH, [redacted] This information is not sufficient for the Court to ascribe any weight to Dr. Cote's opinion based on this purported relevant experience. Regarding Flagship, [redacted] This information is not sufficient for the Court to ascribe any weight to Dr. Cote's opinion based on this purported relevant experience.

In addition to Dr. Cote being unqualified and not credible, his opinion about the process and timeline for commercializing a multicancer screening test is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

1961. [redacted]

[redacted]

Response to Finding No. 1961

[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

1962. [redacted]

Response to Finding No. 1962

[redacted]

[redacted]

[redacted]

1963. Dr. Scott Morton entirely omits consideration of the other features of cancer screening tests in describing the purported product market. But other features of cancer screening tests, such as their ability to detect a cancer signal of origin, are likely to affect which tests are considered substitutable by physicians. [redacted]; RX3869 (Cote Expert Report) ¶ 15); Cote Tr. 3782, [redacted]

Response to Finding No. 1963

[redacted]

[redacted]

1964. Upstream Market. Dr. Scott Morton omits the fact that currently, there are several viable alternative NGS platforms for those cancer screening tests that are now in development, and as outlined further below, there are several more companies on the horizon, and likely even more once certain Illumina patents expire in 2023. (RX3869 (Cote Expert Report) ¶ 15); Cote Tr. 3739–43.)

Response to Finding No. 1964

Complaint Counsel objects to the proposed finding because it is incorrect and misleading, Dr. Cote is not a credible witness, Dr. Cote is not qualified to provide expert opinion testimony on these subjects.

The proposed finding is incorrect and misleading because it falsely states Dr. Scott Morton "omits" consideration of viable alternative NGS platforms. [redacted]

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

Dr. Cote is not qualified to offer an expert opinion about the development and commercialization timeline of next generation sequencers. Dr. Cote has never been "retained as an expert in a case involving next-generation sequencers." (Cote Tr. 3961). Dr. Cote has never developed an NGS platform. (Cote Tr. 3962). Dr. Cote has never worked for a supplier of NGS platforms. (Cote Tr. 3962, 78). Dr. Cote has never done consulting work for NGS instrument

manufacturers related to the development of a next-generation sequencer. (Cote Tr. 3962-63). Dr. Cote does not have a degree related to hardware engineering. (Cote Tr. 3963). Dr. Cote has never designed an NGS instrument prototype. (Cote Tr. 3963). [redacted] Dr. Cote has never written any industry reports about the NGS instrument market. (Cote Tr. 3964). [redacted] Dr. Cote is not an attorney or otherwise trained to perform an analysis of any patent infringement claims Illumina has asserted against BGI. (Cote Tr. 3983).

Dr. Cote is also not qualified to offer an expert opinion about which NGS platforms are viable for MCED testing. Dr. Cote has never personally operated an NGS instrument. (Cote Tr. 3971). There are no next-generation sequencers located in Dr. Cote's research lab. (Cote, Tr. 3966). Dr. Cote has never published *any* research relating to NGS. (Cote Tr. 3972). When asked "Do any of your publications relate to next-generation sequencing?", likely recognizing that it would expose a severe deficiency in his qualifications if he could not answer "yes", Dr. Cote responded, "I have publications related to sequencing", attempting to create the impression that he did have publications related to next-generation sequencing. (Cote Tr. 3972). But when immediately asked again "Do you have publications relating to *next-generation* sequencing?" (emphasis added) he conceded "Not as yet." (Cote, Tr. 3972). Dr. Cote supervises a small research lab employing only approximately six people. (Cote Tr. 3966).

In addition to Dr. Cote being unqualified, his opinions about the development and commercialization of next generation sequencers and which NGS platforms are viable for

MCED testing are unreliable given that his analysis has not been subject to nor is it reflected in any peer-reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. Therefore, this Court should disregard the proposed finding.

1965. It is too speculative and indeed impossible to know at this time to know which provider's platforms will be relied on by cancer screening test developers at the time that such tests are actually commercially available, particularly at wide scale. (RX3869 (Cote Expert Report) ¶ 16.)

Response to Finding No. 1965

Complaint Counsel objects to the proposed finding because Dr. Cote is not qualified to provide expert opinion testimony on these subjects, Dr. Cote's opinion is not reliable, and Dr. Cote is not a credible witness.

Dr. Cote is not qualified to provide expert opinion testimony about [redacted] Dr. Cote is also not qualified to provide expert opinion testimony about [redacted] This Court should not accord Dr. Cote's opinions any weight.

In addition to Dr. Cote being unqualified, his opinions about the development and commercialization of next generation sequencers and which NGS platforms are viable for MCED testing are unreliable given that his analysis has not been subject to nor is it reflected in any peer-reviewed publication, is not supported by any well-known regulatory guidance or

scientific standard, and does not appear to be accepted by any relevant scientific community.

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted] Therefore, this Court should disregard the proposed finding.

1966. [redacted]

Response to Finding No. 1966

[redacted]

- [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

[redacted]

1967. Given these long timeframes, all test developers pursuing cancer screening tests will have the option to switch to other clinical diagnostic platforms, including other NGS platforms, without meaningfully affecting timeframes for development and approval. It is common for test developers to need to switch between sequencing instruments offered by the same platform provider (*e.g.*, different Illumina platforms). Test developers are also able to develop a test in parallel on multiple platforms concurrently. Dr. Cote expects that test developers will be able to switch between different platforms under the same timelines as needed to switch between different Illumina instruments, especially as the platforms slated to launch in the United States in the next few years appear to use chemistry that is reasonably similar to Illumina's sequencing chemistry. (RX3869 (Cote Expert Report) ¶ 18); Cote Tr. 3727–28; 3771–74.)

Response to Finding No. 1967

Complaint Counsel objects to the proposed finding because it improperly cites expert testimony, Dr. Cote is not qualified to provide expert opinion testimony on these subjects, Dr. Cote's opinion is not reliable, Dr. Cote is not a credible witness, and it is against the weight of the evidence.

This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here, Respondents cite Dr. Cote as the only source supporting multiple purely factual contentions—namely, that test developers will have the option to switch NGS platforms, that doing so will not affect their timeframes, that it is common to switch instruments, that developers are able to develop a test in parallel on multiple platforms, and that new NGS platforms are slated to launch in the United States in the next few years that use chemistry similar to Illumina's—in contravention of this Court's Order. Dr. Cote is not a fact witness. This Court should disregard this evidence.

Dr. Cote is not qualified to provide expert opinion testimony about [redacted] Dr. Cote is also not qualified to provide expert opinion testimony about [redacted] This Court should not accord Dr. Cote's opinion[s] any weight.

In addition to Dr. Cote being unqualified, his opinions about the process and timeline for commercializing an MCED test, the development and commercialization of next generation sequencers, and which NGS platforms are viable for MCED testing are unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community.

Dr. Cote is not a credible witness, so his opinion does not deserve any weight. [redacted]

[redacted]

The proposed finding is against the weight of substantial evidence showing that [redacted] This court should not substitute Dr. Cote's unqualified paid opinion for this substantial reliable evidence from market participants about the realities of switching NGS platforms. Therefore, this Court should disregard the proposed finding.

1968. [redacted]

Response to Finding No. 1968

[redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

[redacted]

1969. [redacted]

Response to Finding No. 1969

[redacted]

[redacted]

[redacted]

1970. [redacted]

[redacted]

Response to Finding No. 1970

[redacted]

[redacted]

[redacted]

1971. In addition, Dr. Scott Morton's statement that only NGS-based tests may be used for "MCED" is incorrect. As noted, Dr. Scott Morton's contention that all cancer screening tests capable of simultaneously screening for more than one cancer are substitutable for each other is wrong. Further, while a screening test that will identify 50 types of cancer from a single blood sample that can also identify the cancer signal of origin is likely to use NGS technology, a screening test for fewer types of cancer, particularly two or three types of cancer, can use other diagnostic platforms, such as proteomics, PCR or microarray technology. Based on the evidence that he reviewed, Dr. Cote also anticipates that screening tests that detect fewer cancers are likely to complement a test that identifies 50 types of cancers from a single blood sample. For example, a physician may be interested in using a highly sensitive single cancer screening test for individuals with higher risk for that cancer, a view supported by Dr. Richard Abrams. Blood-based single cancer screening tests are also more likely to replace standard of care screening, whereas GRAIL has stated that its Galleri test would be in addition to guideline standard of care screening. (RX3869 (Cote Expert Report) ¶ 22); Cote Tr. 3777–83, 3807–08, [redacted]

Response to Finding No. 1971

[redacted]

[redacted]

[redacted]

1972. The adoption of and reimbursement for a diagnostic test is influenced by a number of factors, that first of all rests on evidence-based clinical utility, and a variety of important stakeholders. In addition to public and private payors, any cancer screening test developer must attempt to persuade these stakeholders of the clinical utility of their test to achieve widespread adoption of their test. These stakeholders include health technology assessment ("HTA") and advisory bodies, patient advocacy groups, and medical specialty societies. Each of these stakeholders plays an integral role in shaping the treatment pathway and innovation of oncology, thereby influencing reimbursement coverage in addition to utilization of

oncology tests and treatments. Given that development of blood-based cancer screening is in its infancy, and that there are likely to be vastly divergent approaches to cancer screening tests, it is likely to take significant time and resources to educate these groups about novel cancer screening testing technologies, particularly those capable of doing multi-cancer screening, *i.e.*, screening simultaneously for a large number of cancer types, like the Galleri test. (RX3869 (Cote Expert Report) ¶ 23).

Response to Finding No. 1972

Complaint Counsel objects to the proposed finding because it is confusing, unsupported, it improperly cites expert testimony, Dr. Cote is not qualified to offer opinion testimony on these subjects, Dr. Cote is not credible, and Dr. Cote's opinion is not reliable.

The proposed finding is confusing because it strings together multiple purported facts without providing specific citations for each.

The proposed finding is unsupported because for all of the lengthy purported facts contained therein it cites no source other than a single paragraph of Dr. Cote's report, which in turn cites no evidence at all. (RX3869 (Cote Expert Report) ¶ 23 (citing no evidence at all)). This Court ordered that experts shall not be cited to "support factual propositions that should be established by fact witnesses or documents." *See* Order on Post-Trial Findings at 3. Here Respondents cite Dr. Cote as the only source of evidence supporting the purported facts in the proposed finding in contravention of this Court's Order. This Court should disregard this evidence.

The proposed finding is also misleading because—like numerous of Respondents' other proposed findings—the entire paragraph is copied and pasted verbatim from Dr. Cote's report and represents only his opinion rather than market realities. [redacted]

[redacted]

[redacted] In addition, Dr. Cote's opinion about MCED test development and commercialization is unreliable given that his analysis has not been subject to nor is it reflected in any peer reviewed publication, is not supported by any well-known regulatory guidance or scientific standard, and does not appear to be accepted by any relevant scientific community. This Court should not accord Dr. Cote's opinion any weight and disregard the proposed finding.

1973. [redacted]

Response to Finding No. 1973

[redacted]

[redacted]

3. **Patricia Deverka**

a. Background

1974. Dr. Deverka is the Deputy Director of the Center for Translational and Policy Research on Personalized Medicine (TRANSPERS) at the University of California at San Francisco (UCSF) and a Senior Researcher in the School of Pharmacy at UCSF. TRANSPERS

emphasizes interdisciplinary approaches to gather evidence about how genomic information is being integrated into clinical practice. She is also the Executive Director at Deverka Consulting, LLC with a practice focused on helping biotechnology companies and start-ups develop their evidence strategy to support payer coverage and clinical adoption of innovative technologies. Her most recent projects have focused on breakthrough tests and drugs focused on population genomic screening, cancer, and ultra-rare disorders. (RX3867 (Deverka Expert Report) ¶ 1); RX6001 (Deverka Trial Dep. at 7–8).)

Response to Finding No. 1974

Complaint Counsel has no specific response to this proposed finding.

1975. Dr. Deverka holds a Bachelor's degree in Biology from the University of Virginia, a medical degree from the University of Pittsburgh School of Medicine, a master's degree in Preventive Medicine from the University of Maryland and a master's degree in Bioethics from the University of Pennsylvania. Her residency training was in General Preventive Medicine and Public Health and she completed a mid-career policy fellowship at Duke University's Institute for Genome Sciences and Policy in 2007. (RX3867 (Deverka Expert Report) ¶ 2); RX6001 (Deverka Trial Dep. at 8–9).)

Response to Finding No. 1975

Complaint Counsel has no specific response to this proposed finding.

1976. During her professional career, Dr. Deverka worked in the fields of health economics and outcomes research in both non-profit and for-profit settings as a researcher, educator, and department head. From 1990–2004, she created and managed departments of outcomes research in both the pharmaceutical and pharmacy benefit management industries. After completing her policy fellowship at Duke, her career transitioned to academia where she spent several years as a Research Associate Professor at the University of North Carolina at Chapel Hill studying the evidence development pathway for the clinical integration of pharmacogenomics as a member of an interdisciplinary team. (RX3867 (Deverka Expert Report) ¶ 3); RX6001 (Deverka Trial Dep. at 10–15).)

Response to Finding No. 1976

Complaint Counsel has no specific response to this proposed finding.

1977. While working in academia and several non-profit firms from 2008–2020, Dr. Deverka participated in numerous NIH-funded studies to evaluate policy barriers to clinical integration of new genomic technologies and have published extensively on strategies to promote evidence generation, particularly in the areas of payer coverage for NGS-based tests. She is a member of the National Human Genome Research Institute (NHGRI)'s Genomic Medicine Work Group and serves as a member of NHGRI's Scientific Advisory Council. (RX3867 (Deverka Expert Report) ¶ 4); RX6001 (Deverka Trial Dep. at 15–16).)

Response to Finding No. 1977

Complaint Counsel has no specific response to this proposed finding.

1978. Dr. Deverka has published dozens of peer-reviewed articles in medical journals on the topics of payers' evidentiary framework for determining coverage for molecular diagnostics and patient engagement in comparative effectiveness research. She is a referee for a number of medical journals, including Health Affairs, Journal of the National Comprehensive Cancer Network, Journal of Clinical Oncology, Value in Health, Pharmacogenomics, Clinical Pharmacology and Therapeutics, Genetics in Medicine, Personalized Medicine, Journal of Oncology Practice and the Journal of Comparative Effectiveness Research. She is also a member of the International Society of Pharmacoeconomics and Outcomes Research, a professional organization focused on promoting health economics and outcomes research excellence to improve healthcare decision-making. (RX3867 (Deverka Expert Report) ¶ 5); RX6001 (Deverka Trial Dep. at 22–23).)

Response to Finding No. 1978

Complaint Counsel has no specific response to this proposed finding.

b. Summary of Opinions

1979. [redacted]

Response to Finding No. 1979

[redacted]

[redacted]

[redacted]

1980. Developers of MCED tests may find it challenging to receive positive coverage determinations from public and private payors for several reasons. To inform payor decision-making, cancer screening test developers must provide robust evidence of how use of the test affects clinician decision-making and patient outcomes (clinical utility). Clinical utility studies will require large sample sizes due to the low prevalence of individual cancer types in the general population and the need to address concerns regarding the harms of false positives, lead-time bias, and overdiagnosis. These studies will also require sustained patient enrollment over several years to demonstrate significant differences in patient health outcomes for those identified with cancer. These studies must also compare early cancer screening tests to current standard of care cancer screening (including cancers for which the current standard of care (SOC) is no screening). (RX3867 (Deverka Expert Report) ¶ 10); RX6001 (Deverka Trial Dep. at 31–35).)

Response to Finding No. 1980

This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Additionally, the proposed finding is vague, confusing, unsupported, incomplete, misleading, incorrect, and against the weight of the evidence. Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' string citation at the end of their recitation of unrelated statements does not provide clear support for any individual statement.

[redacted]

[redacted]

Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable. Finally, one of the statements reads: "Developers of MCED tests may find it challenging to receive positive coverage determinations from public and private payors for several reasons." [redacted] Therefore, this Court should disregard the proposed finding.

1981. The specific features of MCED tests that represent a potential paradigm shift for cancer screening also create complexities for demonstrating clinical utility to payors. There is no established evidentiary framework for evaluating a test that is designed to detect multiple cancers simultaneously, given varying benefits and harms by tumor type. While a simple blood draw may facilitate screening accessibility and compliance, the effects of MCED tests on patient and provider behavior and adherence to SOC screening are still unclear, complicating payor interpretation of clinical utility. (RX3867 (Deverka Expert Report) ¶ 11); RX6001 (Deverka Trial Dep. at 61–62).)

Response to Finding No. 1981

This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the

Court's Order and 16 C.F.R. § 3.46. Additionally, the proposed finding is vague, confusing, unsupported, incomplete, misleading, incorrect, and against the weight of the evidence. Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' string citation at the end of their recitation of unrelated statements does not provide clear support for any individual statement." [redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable.

The proposed finding is also unsupported and unreliable because Dr. Deverka lacks the foundation and expertise to opine on issues like the alleged "paradigm shift for cancer screening" and specific features of MCED tests, including most notably the "varying benefits and harms by tumor type." [redacted] Further, she readily acknowledges she is not a regulatory expert, (RX6001 (Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). Accordingly, she lacks the foundation and requisite expertise to opine on the standard of care for cancer screening and the potential for MCEDs to gain acceptance by CMS and other payors. Therefore, this Court should disregard the proposed finding.

1982. Any new cancer screening test targeting all average risk adults ages 50–79 years requires compelling evidence of the risks and benefits resulting from test use. And while the

FDA may be focused on evidence that test results accurately identify a patient's clinical status (clinical validity), payors will likely require convincing evidence of clinical utility to cover a new MCED test. This may represent an additional evidence hurdle beyond that set by regulatory authorities. (RX3867 (Deverka Expert Report) ¶ 12); RX6001 (Deverka Trial Dep. at 39–42).)

Response to Finding No. 1982

This Court's Post-Trial Order explicitly requires that all facts be supported by "specific references to the evidentiary record." (*See* Order on Post-Trial Findings at 2). Here, Respondents have improperly merged numerous largely unrelated proposed findings of fact together without providing specific references to the evidentiary record for those individual findings themselves. This proposed composite finding should be disregarded for violating the Court's Order and 16 C.F.R. § 3.46. Additionally, the proposed finding is vague, confusing, unsupported, incomplete, misleading, incorrect, and against the weight of the evidence. Respondents' combination of numerous largely unrelated statements is itself confusing and misleading to the extent Respondents intend to state one fact. Further, Respondents' string citation at the end of their recitation of unrelated statements does not provide clear support for any individual statement. [redacted]

[redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable.

The proposed finding is also improper expert witness testimony that is unsupported, and thus unreliable, which should be wholly disregarded. Respondents include a statement that "while the FDA may be focused on evidence that test results accurately identify a patient's clinical status (clinical validity), payors will likely require convincing evidence of clinical utility

to cover a new MCED test." Dr. Deverka readily acknowledges she is not a regulatory or FDA expert, (RX6001 (Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). Accordingly, she lacks the foundation and requisite expertise to opine on the regulatory pathways for MCED tests. Moreover, the proposed finding is vague and misleading because Respondents have not defined "compelling evidence" the "risks" and "benefits," or "test use" when stating—without any supporting citations—that "[a]ny new cancer screening test targeting all average risk adults ages 50–79 years requires compelling evidence of the risks and benefits resulting from test use." Therefore, this Court should disregard the proposed finding.

1983. MCED tests will not be able to receive Medicare coverage through standard coverage processes due to statutory limitations preventing Medicare from covering most preventive services. In order to receive Medicare coverage, manufacturers of these tests will have to either receive a U.S. Preventive Services Task Force (USPSTF) grade of A or B for their test, or wait for the passage of legislation that adds FDA-approved MCED tests as a Medicare benefit category. (RX3867 (Deverka Expert Report) ¶ 13); RX6001 (Deverka Trial Dep. at 48–52.)

Response to Finding No. 1983

The proposed finding is vague, misleading, confusing, improper expert opinion, unsupported, and unreliable. [redacted]

[redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable. This finding is further unsupported and unreliable because Dr. Deverka lacks the foundation and expertise to opine on the regulatory pathway for MCED tests. Dr. Deverka readily acknowledges she is not a regulatory or FDA expert, (RX6001

(Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). Accordingly, her unsupported views on the USPSTF and FDA processes, along with views on requisite legislation, is improper expert opinion that should be wholly disregarded.

1984. In order to receive Medicare reimbursement, MCED test manufacturers will also need to undergo a payment assignment process for a Medicare payment rate to be set for any new code. Time between initial code application and listing of a code's Medicare payment rate on the Clinical Lab Fee Schedule (CLFS) can take 9–23 months, depending on the code type and application cycle. (RX3867 (Deverka Expert Report) ¶ 14); RX6001 (Deverka Trial Dep. at 47–48.)

Response to Finding No. 1984

The proposed finding is vague, misleading, confusing, improper expert opinion, unsupported, and unreliable. [redacted]

[redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable. This finding is further unsupported and unreliable because Dr. Deverka lacks the foundation and expertise to opine on the regulatory pathway for MCED tests. Dr. Deverka readily acknowledges she is not a regulatory or FDA expert, (RX6001 (Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). Accordingly, her unsupported views on the requirements of Medicare reimbursement and the time necessary to meet these requirements is improper expert opinion that should be wholly disregarded.

1985. Obtaining coverage by private payors will also require an assessment of affordability on top of clinical utility requirements. Because it is anticipated that potentially all average risk adults over the age of 50 would be eligible for MCED testing, private payors will face a sizeable budgetary impact if they choose to cover any MCED screening tests in addition to current SOC screening. Because payor assessment of a product's impact on health outcomes typically does not consider impact past one or two years, payors' coverage assessment may not fully consider the long-term clinical and economic benefits that may result from MCED screening (cost-effectiveness data). (RX3867 (Deverka Expert Report) ¶ 15); RX6001 (Deverka Trial Dep. at 36–39).)

Response to Finding No. 1985

The proposed finding is vague, misleading, confusing, improper expert opinion, unsupported, and unreliable. [redacted]

[redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable. This finding is further unsupported and unreliable because Dr. Deverka lacks the foundation and expertise to opine on the regulatory pathway for MCED tests. Dr. Deverka readily acknowledges she is not a regulatory or FDA expert, (RX6001 (Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). [redacted] Accordingly, her unsupported views on MCED tests, their intended patient population and relationship to current standard-of-care screening tests, and the specific requirements of Medicare reimbursement of MCED tests is improper expert opinion that should be wholly disregarded.

1986. In addition, a substantial amount of resources, expertise, and experience (*e.g.*, payor and health system relationships, market access expertise, and investment in long-term prospective studies) will be essential to deliver robust evidence and engagement for payor decision-making. If successfully executed, this evidence would likely accelerate patient access to MCED tests. Over time, providing real-world evidence of the clinical utility of MCED tests could also potentially lower the barriers to market entry for additional MCED tests. (RX3867 (Deverka Expert Report) ¶ 16); RX6001 (Deverka Trial Dep. at 31–32).)

Response to Finding No. 1986

The proposed finding is vague, misleading, confusing, incomplete, improper expert opinion, unsupported, and unreliable. [redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable. The proposed finding is also vague, misleading, incomplete, and confusing because Respondents have failed to define the words "resources," "expertise," "engagement." These words are all material for understanding the proposed fact—which, again, has no supporting citations in the portion of her report that Respondents directly quote as fact. Accordingly, this fact should be disregarded as incomplete and confusing.

This proposed finding is further unsupported and unreliable because Dr. Deverka lacks the foundation and expertise to opine on acceleration of "patient access to MCED tests" or the "barriers to market entry for additional MCED tests." Dr. Deverka readily acknowledges she is not a regulatory or FDA expert, (RX6001 (Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). [redacted]

Accordingly, she clearly lacks the expertise to opine on patient access to MCED tests. Respondents have also attributed a phrase "barriers to market entry" to Dr. Deverka and her report, which is a term of art used in antitrust law and economics. To the extent Respondents intend to use this term in accordance with its use in antitrust law and economics, the proposed finding is clearly improper expert witness testimony. Dr. Deverka does not have a degree in economics and does not claim to be an industrial organization economist. (RX6001 (Deverka Trial Dep. at 127)). In fact, Dr. Deverka testified she is not even aware of the Horizontal Merger Guidelines ("HMG") issued by the DOJ and FTC and didn't apply them in her report. (RX6001 (Deverka Trial Dep. at 137-38)). Her opinions on barriers to entry are thus improper expert testimony and should be disregarded in their entirety. Therefore, this Court should disregard the proposed finding.

1987. Lack of payor coverage of MCED tests will be a barrier to patient access, particularly for vulnerable groups (*e.g.*, those with known disparities in access to cancer screening, treatment, and the resulting health outcomes). To ensure equitable access to MCED tests will require insurance coverage and ongoing evidence generation efforts that can be more rapidly achieved by a larger company with established expertise and the necessary resources. (RX3867 (Deverka Expert Report) ¶ 17); RX6001 (Deverka Trial Dep. at 55–56; 67–68).)

Response to Finding No. 1987

The proposed finding is vague, misleading, confusing, incomplete, improper expert opinion, unsupported, and unreliable. [redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly disregarded as unsupported and unreliable. The proposed finding is also vague, misleading, incomplete, and confusing because Respondents have failed to define "barriers to patient

access," "equitable access," "evidence generation efforts," "larger company," "established expertise," and "necessary resources." These phrases are all material for understanding the proposed fact—which, again, has no supporting citations in the portion of her report that Respondents have quoted as fact. Accordingly, this fact should be disregarded as incomplete and confusing.

This proposed finding is further unsupported and unreliable because Dr. Deverka lacks the foundation and expertise to opine on the relative capabilities of companies to obtain insurance coverage and pursue "evidence generation efforts," especially as it relates to the relative speed at which these alleged "larger companies" can accomplish both. Most significantly, Respondents have posited as fact that "ensur[ing] equitable access to MCED tests will require insurance coverage and ongoing evidence generation efforts that can be more rapidly achieved by a larger company with established expertise and the necessary resources"—an assertion supported with *only* an uncited portion of Dr. Deverka's report and her trial testimony. This Court's Scheduling Order makes clear that "[e]ach expert report shall include a complete statement of all opinions to be expressed and *the basis and reasons therefor*." This assertion of fact not only directly violates this rule, but also asks the Court to accept as fact an unsupported, and thus unreliable, portion of an expert report.

Even if Respondents had provided a citation to support this assertion, Dr. Deverka lacks the foundation and expertise to form such a conclusion. Dr. Deverka readily acknowledges she is not a regulatory or FDA expert, (RX6001 (Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). [redacted]

[redacted]

Accordingly, she clearly lacks the expertise to opine on patient access to MCED tests. Failure to define or even articulate a standard for evaluating whether a company has "established expertise and the necessary resources" makes this fact even more unreliable and incomplete, as it provides no basis for the Court to analyze the accuracy of the alleged fact. Respondents' failure to abide by the clear rules of the Court's Scheduling Order, on top of the proposed fact's other deficiencies, render this fact wholly unreliable and grounds for it to be disregarded.

1988. [redacted]

Response to Finding No. 1988

[redacted]

[redacted]

[redacted]

1989. Illumina also has extensive relationships with professional societies and advocacy groups that will be essential to ensuring MCED screening is appropriately integrated into screening recommendations and follow-up medical care. Given that the results of MCED tests will require tailored follow-up diagnostic procedures and cancer care referrals across tumor types, MCED test developers will need to engage with specialty medical societies and advocacy groups to properly educate clinicians regarding use and interpretation of MCED tests. (RX3867 (Deverka Expert Report) ¶ 19); RX6001 (Deverka Trial Dep. at 69–71).)

Response to Finding No. 1989

The proposed finding is vague, misleading, confusing, incomplete, improper expert opinion, unsupported, and unreliable. [redacted] Respondent's additional citation to Dr. Deverka's trial testimony does not cure the deficiency as her testimony cannot exceed the scope of her report. Accordingly, Respondents have represented unsupported statements in her report as alleged "facts," which should be wholly

disregarded as unsupported and unreliable. The proposed finding is also vague, misleading, incomplete, and confusing because Respondents have not defined or identified "extensive relationships" as used in the first sentence, as well as the terms "professional societies," "advocacy groups," "screening recommendations," or "tailored follow-up diagnostic procedures and cancer care referrals across tumor types." These terms are all material for understanding the proposed fact—which, again, has no supporting citations in the portion of her report that Respondents have quoted as a fact.

This proposed finding is further unsupported and unreliable because Dr. Deverka lacks the foundation and expertise to opine on the strength of Illumina's relationships with "professional societies and advocacy groups"—much less opine on the relevance of these relationships as it relates to MCED test developers and the acceptance and use of their tests in the market. Dr. Deverka readily acknowledges she is not a regulatory or FDA expert, (RX6001 (Deverka Trial Dep. at 126)), and has never worked at the Centers for Medicare and Medicaid Services ("CMS"), United States Preventative Services Task Force ("USPSTF"), or FDA. (RX6001 (Deverka Trial Dep. at 126)). [redacted] Accordingly, she clearly lacks the expertise to opine on the requirements of an MCED test to gain acceptance from relevant patient groups or Illumina's supposed ability to assist in these efforts. Therefore, this Court should disregard the proposed finding.

1990. [redacted]

[redacted]

Response to Finding No. 1990

[redacted]

[redacted]

[redacted]

4. **Margaret Guerin-Calvert**

a. Background

1991. Margaret E. Guerin-Calvert is the President and Senior Managing Director of FTI Consulting, Inc.'s Center for Healthcare Economics and Policy, a business unit that specializes in healthcare economics and applied microeconomics. She is an industrial organization economist, which is the branch of economics that involves the study of firms, industries, consumer behavior, and pricing. She is also a founding director of Compass (Competition Policy Associates), the predecessor of Compass Lexecon, an independent subsidiary of FTI Consulting, Inc., a firm which specializes in antitrust and applied microeconomics, and she continues to serve as Senior Consultant on selected Compass Lexecon matters. (RX3865 (Guerin-Calvert Expert Report) ¶ 1); RX6002 (Guerin-Calvert Trial Dep. at 7–8).)

Response to Finding No. 1991

Complaint Counsel has no specific response to this proposed finding.

1992. Guerin-Calvert has worked as an economist in public and private sectors on issues related to competition and competition policy involving a variety of industries since 1979. She served as Assistant Chief of the Economic Regulatory Section of the Antitrust Division, U.S. Department of Justice, where, among other matters, she had primary responsibility for healthcare matters, including market power and regulatory analyses. She also served as Economist at the Federal Reserve Board and as an AdjunFct Lecturer at Duke University Institute of Policy Sciences (now Sanford School of Public Policy). Guerin-Calvert has testified as an economic expert in several healthcare antitrust and class action cases, including matters involving branded and generic pharmaceuticals and has served as expert for states, federal government, and private sector clients. As an economic expert, Guerin-Calvert testified on matters involving economic analysis of class certification, merits/liability, and damages, among other issues. Some of these matters involved economic analysis of remedies or consent decrees and their efficacy in addressing competitive concerns while permitting the Transaction. (*See*, e.g., *Federal Trade Commission, et al. v. Arch Coal, Inc., et al*. Case No.1:04CV00534 (JDB); Testimony before Pennsylvania Insurance Department regarding proposed affiliation between Highmark, Inc. and the West Penn Allegheny Health System (April 17, 2012); and Report (Economic Analysis Of Highmark's Affiliation with WPAHS and Implementation of an Integrated Healthcare Delivery System), April 2013). Guerin-Calvert's credentials and experience encompass more than three decades of work in antitrust and regulatory policy, including qualification as an expert economist in the U.S., Canada, and New Zealand, and almost 20 years in healthcare antitrust and policy. (RX3865 (Guerin-Calvert Expert Report) ¶ 2, App. A; RX6002 (Guerin-Calvert Trial Dep. at 7–17).)

Response to Finding No. 1992

Complaint Counsel has no specific response to this proposed finding.

b. Summary of Opinions

1993. The Open Offer's terms effectively address the concerns asserted by Complaint Counsel and Dr. Scott Morton that Illumina will have the incentive and ability to anticompetitively disadvantage GRAIL's rivals once Illumina re-acquires control of GRAIL. The Open Offer provides Illumina's clinical oncology customers with comprehensive, long-term protections against alleged foreclosure conduct (including raising rivals' costs), specifically, concerns about access, pricing, quality and rights to develop distributable in-vitro diagnostic ("IVD") kits on Illumina's FDA-regulated ("Dx") systems. (RX3865 (Guerin-Calvert Expert Report) ¶ 6); RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

Response to Finding No. 1993

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1994. The term "clinical oncology customers" includes any Illumina customer active in the development or commercialization of clinical oncology tests using Illumina's systems who meet the definition of "For-Profit Entity" in the Open Offer, including the entities that Dr. Scott Morton and Complaint Counsel have identified as rivals to GRAIL. (RX3865 (Guerin-Calvert Expert Report) ¶ 6, n. 5); RX6002 (Guerin-Calvert Trial Dep. at 26–27).)

Response to Finding No. 1994

The proposed finding is vague because it fails to define or describe what "active" or means. Additionally, it is unclear who gets to decide whether a clinical oncology customer is "active." The proposed finding relies solely upon the self-serving testimony of Respondents' paid expert, Ms. Guerin-Calvert, and does not cite to any Illumina document or customer testimony to support the definition of "clinical oncology customer[]."

The proposed finding is misleading to the extent it implies that Open Offer includes this definition of "clinical oncology customers." Nowhere in the Open Offer or its amended term is the term "clinical oncology customer" used or defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021); *see also* RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

The proposed finding is misleading to the extent it implies that Illumina is required to follow the definition of "clinical oncology customers" provided by Ms. Guerin-Calvert. Therefore, this Court should disregard the proposed finding.

1995. Guerin-Calvert's opinion is based on her independent evaluation of each of the major elements of the Open Offer. Individually and collectively the Open Offer covers the economically necessary set of terms to prevent the alleged competitive harm arising from the proposed Transaction, addresses the specific economic issues and concerns raised by Complaint Counsel and Dr. Scott Morton (primarily by referencing concerns raised by certain Illumina customers), and provides for effective monitoring and enforceability mechanisms. Specifically, the Open Offer covers all relevant aspects of the alleged competition concerns raised in both the short and long term, provides mechanisms to maximize compliance with those terms, and creates a framework to enable a competitive playing field as the upstream and downstream segments evolve over the duration of the Open Offer. (RX3865 (Guerin-Calvert Expert Report) ¶ 7); RX6002 (Guerin-Calvert Trial Dep. at 21–24).)

Response to Finding No. 1995

[redacted]

[redacted]

1996. The Open Offer provides for firewalls to protect from the dissemination of confidential information from Illumina's Next Generation Sequencing ("NGS") customers to GRAIL and misuse of such confidential information. Illumina commits to both structural separations and policies that ensure against such information exchanges. These types of firewalls and protections have been implemented by the FTC (and other antitrust agencies or regulatory agencies) in vertical transactions with success, and these provisions can be effectively implemented. This supports the conclusion that the firewall provided for in the Open Offer also can be effective here in addressing concerns with anticompetitive information sharing. (RX3865 (Guerin-Calvert Expert Report) ¶ 8); RX6002 (Guerin-Calvert Trial Dep. at 79–85).)

Response to Finding No. 1996

[redacted]

[redacted]

[redacted]

[redacted]

1997. The Open Offer makes use of the same principles that have been implemented in practice with regard to enforcement mechanisms (e.g., incentives or mechanisms to enforce compliance or address issues). The audit and arbitration terms of the Open Offer provide Illumina's clinical oncology customers with effective oversight and enforcement mechanisms to ensure compliance with the Open Offer terms and to effectuate its purpose, i.e., ensuring the proposed Transaction will not harm innovation or result in higher prices as compared to the but-

for world where Illumina does not re-acquire control of GRAIL. The very public aspect of the Open Offer can also bolster compliance. (RX3865 (Guerin-Calvert Expert Report) ¶ 9); RX6002 (Guerin-Calvert Trial Dep. at 86–92).)

Response to Finding No. 1997

[redacted]

[redacted]

[redacted]

1998. The firewall and audit terms in the Open Offer are not novel or unusual provisions. Regulatory agencies, including the FTC, and private parties use these types of

compliance or reporting audits regularly in transactions and consent decrees concerning challenged transactions. Illumina has already worked to operationalize the procedures necessary to comply with and audit the Open Offer terms. (RX3865 (Guerin-Calvert Expert Report) ¶ 10); RX6002 (Guerin-Calvert Trial Dep. at 79–85).)

Response to Finding No. 1998

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1999. Illumina also presented the FTC with a set of unilateral behavior commitments in the form of consent principles on February 26, 2021 ("Consent Principles"), which would grant the FTC oversight, monitoring, and access authority post-acquisition—all features commonly used by the FTC in remedial consent decrees. Specifically, the Consent Principles would (i) permit the FTC to appoint a monitor trustee, (ii) provide for submission of an annual verified written report to the FTC regarding Illumina's compliance with the Consent Principles, and (iii) grant FTC access to Illumina books, records, officers, directors and employees to determine or secure compliance with the Consent Principles. The Consent Principles provide additional evidence of Illumina's commitments to openness and compliance, which comport with the FTC's commonly accepted practice of putting in place such consent decrees. (RX3865 (Guerin-Calvert Expert Report) ¶ 11); RX6002 (Guerin-Calvert Trial Dep. at 95–98).)

Response to Finding No. 1999

[redacted]

[redacted]

[redacted]

2000. In addition to effectively codifying the pre-merger status quo, the Open Offer represents an improvement over the status quo for customers, based on the current provisions governing relationships, pricing, and access for customers (focusing in particular on those customers discussed in Dr. Scott Morton's report) compared to those in the Open Offer. (RX3865 (Guerin-Calvert Expert Report) ¶ 12); RX6002 (Guerin-Calvert Trial Dep. at 29–75).)

Response to Finding No. 2000

[redacted]

[redacted]

2001. The Open Offer terms provide commitments that did not exist prior to Illumina's announcement of the Transaction and which benefit Illumina's clinical oncology customers. For example, customers under the Open Offer are assured equivalent access to Supplied Products, access which will not favor GRAIL over other customers, including in times of scarce supply. The Open Offer also offers clinical oncology customers access to standard pricing, which for many customers will be more favorable than current pricing terms. The Open Offer provides for customers to have the option to keep their pricing terms that are in effect as of the GRAIL Transaction ("Transaction") closing. These are relevant improvements. (RX3865 (Guerin-Calvert Expert Report) ¶ 13); RX6002 (Guerin-Calvert Trial Dep. at 34–48).)

Response to Finding No. 2001

[redacted]

[redacted]

[redacted]

2001.1 Supplied Products is defined in the Open Offer as Illumina's NextSeq, NextSeqDx and NovaSeq instruments, and any future sequencing instruments launched by Illumina or its Affiliates, or Sequencing Consumables, which are consumables intended by Illumina to be used to perform a sequencing process on any of these instruments. (RX3865 (Guerin-Calvert Expert Report) ¶ 13, n. 6).

Response to Finding No. 2001.1

The proposed finding is misleading and incorrect because the Open Offer's definition of "Supplied Product(s)" does not state that "sequencing consumables" are "consumables intended by Illumina to be used to perform a sequencing process on any of these instruments." (PX0064 at 004-005 (Illumina, Open Offer Letter, Mar. 29, 2021)). Additionally, the proposed finding is misleading to the extent it implies that Illumina cannot change what a product is. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

2002. [redacted]

[redacted]

Response to Finding No. 2002

[redacted]

[redacted]

2003. [redacted]

Dr. Scott Morton also fails to evaluate the commitments in the Consent Principles, which provides monitoring and reporting commitments similar to many of the FTC's consent decrees in other matters. Dr. Scott Morton reaches her opinions based on an incorrect but-for world and post-Transaction world with the Open Offer that misstates the changes in incentives and ability of Illumina from the but-for world. She conducts no independent analysis of the specific terms or enforceability of the Open Offer and instead relies on selected testimony of third parties. These include testimony about potential unknown circumstances or the ability of contracts to cover all possible theoretical states of the world and contingencies, as well as speculation about theoretical ways Illumina could circumvent the Open Offer that she has not demonstrated are plausible or not addressed by the audit and arbitration mechanisms in the Open Offer. The Scott Morton report also provides inconsistent economic analyses of Illumina's supposed ability to reach complex contractual agreements with customers governing longer and shorter term risks and uncertainties, while asserting that the detailed provisions of the Open Offer governing multiple aspects of contracts are incomplete, inadequate, and unable to address customer issues. (RX3865 (Guerin-Calvert Expert Report) ¶ 15); RX6002 (Guerin-Calvert Trial Dep. at 103–105).)

Response to Finding No. 2003

[redacted]

[redacted]

2004. Complaint Counsel also asserts that the Open Offer is deficient in that it is not enforceable with regard to firewalls or compliance (audits), although Complaint Counsel and Dr. Scott Morton do not address the specific provisions of the Open Offer, provide evidence of non-enforceability or insufficiency of the terms, or distinguish use of firewalls in the multiple other matters in which the FTC (or other agencies) have used them. These are largely generalized concerns and statements of potential concerns and not detailed analysis of the specifics of the Open Offer and how it might (and does) address them. Nor is Dr. Scott Morton consistent in the weight she places on third-party testimony. [redacted]

Response to Finding No. 2004

[redacted]

[redacted]

[redacted]

2005. The Open Offer provides for the Transaction's benefits to occur, which are lost if the Transaction is stopped. The Transaction occurs in a developing marketplace where there are no *a priori* assurances or guarantees about commercial outcomes or the identity or number of successful innovators. These factors are highly relevant to Illumina's incentives post-Transaction to continue to work with GRAIL's rivals and the protections afforded to them and to the assessment of the competitive effects of the Transaction with the Open Offer. They also are relevant to the standard principles applied in crafting remedies in vertical transactions or in private arrangements between vertically-aligned companies with multiple downstream companies, including in developing markets or ones with potentially many different outcomes—namely, of achieving the benefits of the Transaction while effectively addressing the competitive concerns. (RX3865 (Guerin-Calvert Expert Report) ¶ 17.)

Response to Finding No. 2005

[redacted]

[redacted]

5. **Robert Willig**

a. Background

2006. Robert Willig is a Professor of Economics and Public Affairs Emeritus at Princeton University, where he held a joint appointment in the Economics Department and at the Woodrow Wilson School of Public and International Affairs from 1978 to 2016, and continued to teach the graduate course "Legal and Regulatory Policy Toward Markets". His teaching and research have specialized in the fields of industrial organization (the field that includes antitrust), government-business relations, and social welfare theory. He served as Deputy Assistant Attorney General for Economics in the Antitrust Division of the U.S. Department of Justice from 1989 to 1991, and in that capacity served as the Division's Chief Economist. (RX3871 (Willig Expert Report) ¶ 1.)

Response to Finding No. 2006

Complaint Counsel objects to this proposed finding as supported only by improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel did not have an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination,

presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as based on improper expert opinion.

2007. Mr. Willig authored some 80 articles in the economics literature and is the author of "Welfare Analysis of Policies Affecting Prices and Products" and "Contestable Markets and the Theory of Industry Structure" (with W. Baumol and J. Panzar). He is also a co- editor of "The Handbook of Industrial Organization", which summarizes the state of economic thinking on the structure of industries and the nature of competition among firms, and has served on the editorial boards of the American Economic Review, the Journal of Industrial Economics, and the MIT Press Series on Regulation. He is an elected Fellow of the Econometric Society and was an associate of The Center for International Studies. (RX3871 (Willig Expert Report) ¶ 2.)

Response to Finding No. 2007

Complaint Counsel objects to this proposed finding as supported only by improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's

order and prejudices Complaint Counsel as Complaint Counsel had no opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

2008. Mr. Willig appeared as an expert witness before Congress, federal and state courts, federal administrative agencies, and state public utility commissions on subjects involving competition, regulation, intellectual property rights, and antitrust. He also served as a consultant to the Federal Trade Commission, the U.S. Department of Justice, OECD, the World Bank, the Inter-American Development Bank and many leading corporations on antitrust, regulation, and economic policy issues arising in a wide variety of industries in the United States and around the world. (RX3871 (Willig Expert Report) ¶ 3.)

Response to Finding No. 2008

Complaint Counsel objects to this proposed finding as based solely on improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz

Trial Dep.).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

Respondents' proposed finding is misleading in that it implies that Dr. Willig is not a paid, testifying expert. Compass Lexecon bills for Dr. Willig's time at an hourly rate of $1,450 per hour. Dr. Willig billed between $174,000 and $188,500 to prepare his expert report. (PX7132, Willig Dep. 42-43).

b. Summary of Opinions

2009. Alleged Relevant Market. Prof. Scott Morton has failed to define the relevant product market reliably. (RX3871 (Willig Expert Report) ¶ 6.)

Response to Finding No. 2009

Complaint Counsel objects to this proposed finding as based solely on improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert

Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel had no opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

[redacted]

2010. Prof. Scott Morton's methodology is speculative because it is based on projections about the highly uncertain characteristics of products that are years away from being commercialized and on projections about the identities of competitors whose products are uncertain. (RX3871 (Willig Expert Report) ¶ 6).

Response to Finding No. 2010

Complaint Counsel objects to this proposed finding as based solely on an improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

Respondents' proposed finding is also impermissibly vague. Dr. Willig provides no detail about how an overly broad MCED market would impact Dr. Scott Morton's analysis.

[redacted]

2011. [redacted]

[redacted]

Response to Finding No. 2011

[redacted]

[redacted]

[redacted]

2012. Prof. Scott Morton ignores the conduct and influence of payors when defining the relevant product market. Including them in the analysis shows that Prof. Scott Morton has failed to establish that existing cancer screening methods should be excluded from the relevant product market. (RX3871 (Willig Expert Report) ¶ 6.)

Response to Finding No. 2012

Complaint Counsel objects to this proposed finding as improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.)).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

2013. Timing is a key dimension of the putative MCED test product market because the claimed "related product", namely Illumina's NGS platform, is part of a highly dynamic market subject to its own important changes over time. The timing of the putative MCED test products is highly uncertain and Prof. Scott Morton has not established that their purported market will come into existence with all or most of the products and rivals of GRAIL identified by Prof.

Scott Morton at a time when there may be no viable alternative to the related product supplied by Illumina. (RX3871 (Willig Expert Report) ¶ 6.)

Response to Finding No. 2013

Complaint Counsel objects to this proposed finding as based on improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

2014. Alleged Anticompetitive Effects. Complaint Counsel's theories of anticompetitive effects are belied by the actions of firms in the marketplace. (RX3871 (Willig Expert Report) ¶ 7.)

Response to Finding No. 2014

Complaint Counsel objects to this proposed finding as based on improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designate Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

[redacted]

2015. Complaint Counsel's theory undergirding the proposed merger's purported anticompetitive effects presupposes that there will be no viable substitutes to Illumina's NGS platforms to which GRAIL's potential competitors in the purported MCED test relevant market could readily switch in response to Illumina increasing its prices or engaging in foreclosure. (RX3871 (Willig Expert Report) ¶ 7.)

Response to Finding No. 2015

Complaint Counsel objects to this proposed finding as an improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination,

presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

Respondents' proposed finding is misleading to the extent it implies that either (a) there are current alternative platforms available for MCED test developers; or (b) that MCED test developers will have access to alternative platforms soon enough to offset the anticompetitive harm resulting from this merger. As Dr. Willig admitted, he is unaware of any non-Illumina NGS sequencer that is currently available for sale. (PX7132 (Willig Dep. 203)). [redacted] Therefore, this Court should disregard the proposed finding.

2016. Complaint Counsel's presupposition is inherently speculative. Multiple companies are developing NGS platforms that they expect will effectively compete with Illumina's NGS platform within the next several years. This is relevant because many of the companies that Complaint Counsel has identified as GRAIL's potential MCED test rivals do not expect to finish developing and commercializing their MCED tests for at least several years. (RX3871 (Willig Expert Report) ¶ 7.)

Response to Finding No. 2016

Complaint Counsel objects to this proposed finding as improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted]

[redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

Respondents' proposed finding is misleading to the extent it implies that either (a) there are current alternative platforms available for MCED test developers; or (b) that MCED test developers will have access to alternative platforms soon enough to offset the anticompetitive harm resulting from this merger. As Dr. Willig admitted, he is unaware of any non-Illumina NGS sequencer that is currently available for sale. (PX7132 (Willig Dep. 203)). [redacted]

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

2017. [redacted]

Response to Finding No. 2017

[redacted]

[redacted]

2018. Illumina's willingness to pay $8.3 billion for the outstanding shares of GRAIL also would not make economic sense if Illumina expected that it would be able to extract most of the returns from GRAIL's sales of NGS-based cancer screening tests, including Galleri, by then increasing the prices of the essential NGS platforms that it would sell to GRAIL. Thus,

Illumina's willingness to pay such a large sum for GRAIL strongly suggests that Illumina expects its ability to raise prices substantially in the future will be constrained. This conclusion is further supported by the underlying assumptions driving Illumina's valuation of GRAIL, which have GRAIL earning a much larger share of the total profits from sales of its MCED tests than Illumina throughout the period analyzed in the valuation model (which ends in 2035). (RX3871 (Willig Expert Report) ¶ 7.)

Response to Finding No. 2018

Complaint Counsel objects to this proposed finding as improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.)). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as

improper expert opinion.

Respondents present no factual evidence—not even self-serving testimony from their executives—to establish the assumptions underlying their expert's reasoning. [redacted] Moreover, Respondents elicited no evidence that Illumina was "willing[] to pay such a large sum for Grail" because it "expect[ed] its ability to raise prices substantially in the future will be constrained." (Resp. Post-Trial Brief at 129-30.) And they provide no factual support for the assumption that "Illumina would be able to extract most of the returns from GRAIL's commercialized sales of NGS -based cancer screening tests." Resp. Post-Trial Brief at 129. [redacted]

The overwhelming record evidence contradicts Respondents' theory. Despite Respondents' characterization that their theory posits "real world facts," Resp. Post-Trial Brief 130, they offer none.

Even setting aside the absence of any factual moorings to Respondents' theory, the theory itself is flawed. [redacted]

[redacted] Other economic models are consistent with Complaint Counsel's case. Thus, Respondents' theory is an edge case that is conceptually unrealistic and unsupported by any facts suggesting it applies here. This Court should disregard the proposed finding.

2019. Bargaining. Prof. Scott Morton's analysis of the impact of the proposed acquisition through the economic theory of bargaining or negotiation is flawed and fails to establish that the proposed transaction would substantially lessen competition. (RX3871 (Willig Expert Report) ¶ 8.)

Response to Finding No. 2019

Complaint Counsel objects to this proposed finding as based on improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz

Trial Dep.)).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

[redacted] Therefore, this Court should disregard the proposed

finding.

2020. Prof. Scott Morton's bargaining example is based on a model that is unrelated to the key characteristics of the market that she and Complaint Counsel otherwise assume. (RX3871 (Willig Expert Report) ¶ 8.)

Response to Finding No. 2020

Complaint Counsel objects to this proposed finding as based on improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designate Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel had no opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as

improper expert opinion.

[redacted] Therefore, this Court should disregard the proposed finding.

2021. Even more striking is the fact that Prof. Scott Morton's conclusions within her own analytic frame are completely reversed with the addition of only one additional element—namely the availability of either an alternative upstream source or an ex ante supply agreement offer. (RX3871 (Willig Expert Report) ¶ 8.)

Response to Finding No. 2021

Complaint Counsel objects to this proposed finding as based on improper expert opinion offered in contravention of this Court's order. Dr. Willig submitted an expert report as well as deposition testimony. (*See,* (RX3871 (Willig Expert Report); (PX7132, (Willig

Dep.))). [redacted] Accordingly, Respondents asked the Court to allow them to substitute a new expert to "step into Dr. Willig's shoes." (Mot. for Leave to Substitute a Replacement Expert Witness, 2). The Court granted Respondents' narrow request holding that Respondents may *substitute* a new expert for Dr. Willig. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4). Pursuant to this Court's order, Respondents designated Dr. Michael Katz as their replacement expert. Dr. Katz submitted his own expert report and later testified by trial deposition. (*See* PX6105 (Katz Expert Report); RX6004 (Katz Trial Dep.).

Respondents' continued reliance on Dr. Willig's expert opinions contravenes this Court's order and prejudices Complaint Counsel as Complaint Counsel has not an opportunity to cross examine this witness at trial in violation of Complaint Counsel's rights under this Court's Rules. *See* Rule 3.41 (c) ("Every party . . . shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."). As such, Respondents' proposed finding should be disregarded in its entirety as improper expert opinion.

[redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

6. **Robert Rock**

a. Background

2022. Robert Rock is a Managing Director at AlixPartners, LLP ("AlixPartners"). He has been with AlixPartners for approximately 27 years. Prior to joining AlixPartners, he was with Price Waterhouse for 18 years. During his last seven years at Price Waterhouse, he was a partner. (RX3870 (Rock Expert Report) ¶ 1; RX6003 (Rock Trial Dep. at 9).)

Response to Finding No. 2022

[redacted]

[redacted]

2023. Mr. Rock has a bachelor's degree in business administration with a concentration in accounting and an MBA from the University of Michigan. He has been a Certified Public Accountant since 1978. (RX3870 (Rock Expert Report) ¶ 2; RX6003 (Rock Trial Dep. at 8–9).)

Response to Finding No. 2023

[redacted]

2024. While he was at Price Waterhouse, he directed audit engagements of public and private companies and provided professional business consulting services to companies in a variety of industries. (RX3870 (Rock Expert Report) ¶ 3.);

Response to Finding No. 2024

[redacted]

2025. His current practice areas at AlixPartners include investigative/forensic accounting, business consulting, and litigation consulting in commercial matters. He has testified as an expert witness in many cases. (RX3870 (Rock Expert Report) ¶ 4; RX6003 (Rock Trial Dep. at 10–11).)

Response to Finding No. 2025

[redacted]

2026. Mr. Rock has been engaged by the U.S. Department of Justice and the Securities and Exchange Commission as a litigation consultant or expert witness on numerous matters. In addition, he has been appointed as a Receiver, Arbitrator, Special Master or Funds Custodian by federal judges in seven different matters. (RX3870 (Rock Expert Report) ¶ 5; RX6003 (Rock Trial Dep. at 10–11).)

Response to Finding No. 2026

[redacted]

b. Summary of Opinions

2027. An independent auditor or consultant can be effective in examining an entity's compliance with various terms of contracts, performing agreed-upon procedures related to an entity's compliance with specified terms, and performing agreed-upon procedures related to an entity's internal controls over compliance with specified terms. (RX3870 (Rock Expert Report) ¶ 11; RX6003 (Rock Trial Dep. at 29–30).)

Response to Finding No. 2027

[redacted]

7. **Richard Abrams**

a. Background

2028. Dr. Richard S. Abrams is a primary care physician and founder of Colorado Preventative Medicine, where he has practiced Internal Medicine. He is also affiliated with the Rose Medical Center. He also serves on the clinical faculty at the University of Colorado School of Medicine. Dr. Abrams holds a Bachelor's Degree from Northwestern University and a Doctorate of Medicine from the University of Missouri School of Medicine (Columbia). In addition, he currently serves on GRAIL, Inc.'s ("GRAIL") clinical advisory board, where he has served as a thought partner. (PX6097 (Abrams Expert Report) ¶ 1; Abrams Tr. 3601–02.)

Response to Finding No. 2028

The proposed finding is misleading and partially inaccurate. It suggests that Dr. Abrams practices any or all specialties within "primary care" other than internal medicine, which Dr. Abrams acknowledged is "considered a form of primary care" that does not constitute the whole of primary care. (Abrams Tr. 3602–03.) Dr. Abrams testified that "there are other fields of medicine than internal medicine that provide primary care" and that primary care also includes "[p]hysicians who are board-certified in family medicine," "[p]ediatricians," and "obstetrician/gynecologists." (Abrams Tr. 3603–04, 3672–73.) [redacted] Therefore, this Court should disregard the proposed finding.

2029. Dr. Abrams has been a primary care physician at Colorado Preventative Medicine since 2006, when the health organization was first founded. Before founding Colorado Preventative Medicine, he practiced as an internist focusing on preventive medicine. (PX6097 (Abrams Expert Report) ¶ 2; Abrams Tr. 3605–06.)

Response to Finding No. 2029

The proposed finding is misleading, insofar as it suggests that Dr. Abrams practices any or all specialties within "primary care" other than internal medicine, which Dr. Abrams acknowledged is "considered a form of primary care" that does not constitute the whole of

primary care. (Abrams Tr. 3602–03.) Dr. Abrams testified that "there are other fields of medicine than internal medicine that provide primary care" and that primary care also includes "[p]hysicians who are board-certified in family medicine," "[p]ediatricians," and "obstetrician/gynecologists." (Abrams Tr. 3603–04, 3672–73.) [redacted] Therefore, this Court should disregard the proposed finding.

2030. Dr. Abrams has written and edited several books and numerous articles on medical problems during pregnancy, including *Will It Hurt the Baby*, which was featured on the NBC Today Show, ABC Good Morning America, and CBS This Morning. He is board certified in Internal Medicine. (PX6097 (Abrams Expert Report) ¶ 3.)

Response to Finding No. 2030

Complaint Counsel does not disagree with this proposed finding.

2031. During the 44 years Dr. Abrams has practiced medicine, he has regularly performed physical exams and treated a wide spectrum of common illnesses in adults. A large portion of his current practice is devoted to identification and management of risk factors for cardiovascular disease and early detection of cancer. (PX6097 (Abrams Expert Report) ¶ 4; Abrams Tr. 3602; 3605–06.)

Response to Finding No. 2031

The proposed finding is incorrect insofar as it states that Dr. Abrams has practiced medicine for 44 years. [redacted]

b. Summary of Opinions

2032. In summary, Dr. Abrams concluded that primary care physicians play a key role in cancer screening today and will be primarily responsible for recommending MCED tests as they become commercially available and reimbursable in the future. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3613–15.)

Response to Finding No. 2032

[redacted]

[redacted]

[redacted]

[redacted]

2033. Primary care physicians will consider a variety of factors when recommending or ordering a cancer screening test, including the patient's risk factors for a particular cancer, the cancers that the test will be able to detect, the test specificity and sensitivity and other capabilities of the test, the cost of the test to the patient, the health risks associated with the test (*e.g.*, the invasiveness of the test, exposure to radiation, and other considerations), as well as published research studies that support the validity of the test. Primary care physicians will consider these factors when recommending or prescribing a multi-cancer screening test and will also need to decide whether any given multi-cancer screening test can be used as a substitute for or complement to other screening options. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3614–15.)

Response to Finding No. 2033

[redacted]

[redacted]

[redacted]

[redacted]

2034. Although the technology is still in the early stages of development, the most important attributes of an MCED test for primary care physicians will be a test's ability to detect the presence of a cancer and site of origin, the number of cancers detected, and the opportunity to treat early-stage cancer. Primary care physicians will also likely consider the cost to patients of prescribing a given multi-cancer screening test as compared to other multi-cancer and single-cancer options. The attributes that weigh most heavily will vary based on a patient's particular risk factors and may in some cases support the use of complementary screening tests. For example, it may be appropriate for a patient at a higher risk of lung cancer to be screened with a test that has demonstrated high sensitivity and specificity for lung cancer in conjunction with a

multi-cancer screening test that is appropriate for asymptomatic individuals. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3623–28.)

Response to Finding No. 2034

[redacted]

[redacted]

[redacted]

2035. [redacted]

[redacted]

Response to Finding No. 2035

Complaint Counsel does not disagree with this proposed finding.

2036. [redacted]

Response to Finding No. 2036

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

2037. [redacted]

Response to Finding No. 2037

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

2038. [redacted]

Response to Finding No. 2038

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

2039. It is difficult to predict what options there will be for early cancer screening in the future. Dr. Abrams can evaluate what factors will likely be relevant to him as a primary care physician in selecting and using a screening test, but he cannot evaluate whether any particular test will be a viable option several years from now or what new tests may be developed. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3639–40.)

Response to Finding No. 2039

[redacted]

[redacted]

[redacted]

8. **Michael L. Katz**

a. Background

2040. Michael L. Katz is the Sarin Chair Emeritus in Strategy and Leadership at the University of California at Berkeley. He holds a joint emeritus appointment in the Haas School of Business Administration and in the Department of Economics. He also served on the faculties of the Department of Economics at Princeton University and the Stern School of Business at New York University. Dr. Katz received his A.B. from Harvard University *summa cum laude* and a doctorate from Oxford University. Both degrees are in Economics. (PX6105 (Katz Expert Report) ¶ 2; RX6004 (Katz Trial Dep. at 8–9).)

Response to Finding No. 2040

Complaint Counsel objects to Respondents' proposed finding as it relies on the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In those forty to fifty hours, he allegedly read two expert depositions, expert trial testimony, twenty-two depositions and investigative hearing transcripts in whole or in part, thirteen party documents, three third-party documents, and the experts reports in this case. (RX6004 (Katz Trial Dep. at 137-141)). In total, Dr. Katz considered over 6,533 pages of material listed in his materials considered page. In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this

Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted] Therefore, this Court should disregard the proposed finding.

2041. Dr. Katz specializes in the economics of industrial organization, which includes the study of antitrust and regulatory policies. He is the co-author of a microeconomics textbook, and has published numerous articles in academic journals and books. He has written academic articles on issues regarding the economics of network industries, intellectual property, and antitrust policy enforcement, including the antitrust economics of healthcare. He is also a co-editor of the Journal of Economics and Management Strategy and serves on the editorial board of Information Economics and Policy. (PX6105 (Katz Expert Report) ¶ 3; RX6004 (Katz Trial Dep. at 10–11).)

Response to Finding No. 2041

Complaint Counsel objects to Respondents' proposed finding as it relies on the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In those forty to fifty hours, he allegedly read two expert depositions, expert trial testimony, twenty-two depositions and investigative hearing transcripts in whole or in part, thirteen party documents, three third-party documents, and the experts reports in this case. (RX6004 (Katz Trial Dep. at 137-141)). In total, Dr. Katz considered over 6,533 pages of

material listed in his materials considered page. In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted])

Therefore, this Court should disregard the proposed finding.

2042. In addition to his academic experience, Dr. Katz has held several positions in government. From January 1994 through January 1996, he served as the Chief Economist of the Federal Communications Commission. From September 2001 through January 2003, he served as the Deputy Assistant Attorney General for Economic Analysis at the U.S. Department of Justice. His title as Deputy Assistant Attorney General notwithstanding, he is not an attorney. Dr. Katz is currently a Senior Fellow in the Office of Healthcare Transformation in the Ministry of Health of Singapore. (PX6105 (Katz Expert Report) ¶ 4; RX6004 (Katz Trial Dep. at 11–12).)

Response to Finding No. 2042

Complaint Counsel objects to Respondents' proposed finding as it relies on the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz

Trial Dep. at 137)). In those forty to fifty hours, he allegedly read two expert depositions, expert trial testimony, twenty-two depositions and investigative hearing transcripts in whole or in part, thirteen party documents, three third-party documents, and the experts reports in this case. (RX6004 (Katz Trial Dep. at 137-141)). In total, Dr. Katz considered over 6,533 pages of material listed in his materials considered page. In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023**).** Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted])

Therefore, this Court should disregard the proposed finding.

2043. Dr. Katz has consulted on the application of economic analysis to issues of antitrust and regulatory policy for both private and governmental clients. He has served as a consultant to the U.S. Department of Justice, U.S. Federal Trade Commission (including the review of three mergers regarding healthcare products and care providers), and U.S. Federal Communications Commission on competition issues, and he has served as an expert witness before state and federal courts. He has also provided expert testimony before state regulatory commissions and the U.S. Congress. (PX6105 (Katz Expert Report) ¶ 5; RX6004 (Katz Trial Dep. at 11–13).)

Response to Finding No. 2043

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023**).** Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion and the proposed finding should be disregarded.

b. Summary of Opinions

2044. Alleged Relevant Market. Prof. Scott Morton has failed to define the relevant product market reliably. (RX3871 (Willig Expert Report) ¶ 6); PX6105 (Katz Expert Report) ¶ 9; RX6004 (Katz Trial Dep. at 15).)

Response to Finding No. 2044

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness at 004 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report.");

[redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents' proposed finding is against the overwhelming weight of the evidence. [redacted]

[redacted] Therefore, this Court should disregard the proposed finding.

2045. Prof. Scott Morton's methodology is speculative because it is based on projections about the highly uncertain characteristics of products that are years away from being commercialized and on projections about the identities of competitors whose products are uncertain. (RX3871 (Willig Expert Report) ¶ 6; RX6004 (Katz Trial Dep. at 17–26).)

Response to Finding No. 2045

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]

[redacted]

[redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

[redacted]

[redacted]

2046. [redacted]

Response to Finding No. 2046

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to

Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents' proposed finding is also incorrect as a matter of economics and against the overwhelming weight of the evidence. Dr. Willig himself admits that products can compete on the basis of differentiated features and that a merger between firms selling differentiated products may diminish competition. (PX7132 (Willig Dep. at 84)). [redacted]

[redacted]

[redacted]

2047. Prof. Scott Morton ignores the conduct and influence of payors when defining the relevant product market. Including them in the analysis shows that Prof. Scott Morton has failed to establish that existing cancer screening methods should be excluded from the relevant product market. (RX3871 (Willig Expert Report) ¶ 6; RX6004 (Katz Trial Dep. at 31–34).)

Response to Finding No. 2047

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023**).** Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to

Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded. Moreover, Dr. Katz's opinion is against the weight of the evidence. [redacted]

2048. Timing is a key dimension of the putative MCED test product market because the claimed "related product", namely Illumina's NGS platform, is part of a highly dynamic market subject to its own important changes over time. The timing of the putative MCED test products is highly uncertain and Prof. Scott Morton has not established that their purported market will come into existence with all or most of the products and rivals of GRAIL identified by Prof. Scott Morton at a time when there may be no viable alternative to the related product supplied by Illumina. (RX3871 (Willig Expert Report) ¶ 6; [redacted]

Response to Finding No. 2048

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends

approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents' proposed finding is also against the overwhelming weight of the evidence. [redacted]

[redacted] Dr. Willig, however, admits that in an innovation case the ultimate goal of market definition is to help determine whether the merger may substantially lessen innovation. (PX7132 (Willig Dep. at 76-77)). Dr. Willig also agreed that here, MCED test developers are undertaking their activities and committing resources today in the hope and aspiration that they will be able to succeed in the marketplace by selling the product resulting from their development efforts. (PX7132 (Willig Dep. at 103)). [redacted]

2049. Alleged Anticompetitive Effects. The Complaint Counsel's theories of anticompetitive effects are belied by the actions of firms in the marketplace. (RX3871 (Willig Expert Report) ¶ 7; RX6004 (Katz Trial Dep. at 36; [redacted]

Response to Finding No. 2049

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory

review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents' proposed finding also is contradicted by the weight of the evidence. Respondents present no factual evidence—not even self-serving testimony from their executives—to establish the assumptions underlying their expert's reasoning. [redacted] Moreover, Respondents elicited no evidence that Illumina was "willing[] to pay such a large sum for Grail" because it "expect[ed] its ability to raise prices substantially in the future will be constrained." (Resp. Post-Trial Brief at 129-30.) And they provide no factual support for the assumption that "Illumina would be able to extract

most of the returns from GRAIL's commercialized sales of NGS -based cancer screening tests." (Resp. Post-Trial Brief at 129) [redacted]

The overwhelming record evidence contradicts Respondents' theory. Despite Respondents' characterization that their theory posits "real world facts," Resp. Post-Trial Brief 130, they offer none.

[redacted]

2050. Complaint Counsel's theory undergirding the proposed merger's purported anticompetitive effects presupposes that there will be no viable substitutes to Illumina's NGS platforms to which GRAIL's potential competitors in the purported MCED test relevant market could readily switch in response to Illumina increasing its prices or engaging in foreclosure. (RX3871 (Willig Expert Report) ¶ 7; RX6004 (Katz Trial Dep. at 42–48).)

Response to Finding No. 2050

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the

biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents' proposed finding is misleading to the extent it implies that either (a) there are current alternative platforms available for MCED test developers; or (b) that MCED test developers will have access to alternative platforms soon enough to offset the anticompetitive harm resulting from this merger. As Dr. Willig (whose opinion Dr. Katz is bound by) admitted,

he is unaware of any non-Illumina NGS sequencer that is currently available for sale. (PX7132 (Willig Dep. at 203)). [redacted] MCED test developers explained that they need and rely on Illumina NGS as their only NGS option. (CCFF, V(D)(2)). The overwhelming weight of the evidence also shows that any potential entry will not be likely, timely, or sufficient to offset the competitive harm of this transaction. (CCFF, VIII(B)). Therefore, this Court should disregard the proposed finding.

2051. Complaint Counsel's presupposition is inherently speculative. Multiple companies are developing NGS platforms that they expect will effectively compete with Illumina's NGS platform within the next several years. This is relevant because many of the companies that Complaint Counsel has identified as GRAIL's potential MCED test rivals do not expect to finish developing and commercializing their purported MCED tests for at least several years. (RX3871 (Willig Expert Report) ¶ 7; PX6105 (Katz Expert Report) ¶ 9.)

Response to Finding No. 2051

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to

Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents' proposed finding is misleading to the extent it implies that either (a) there are current alternative platforms available for MCED test developers; or (b) that MCED test developers will have access to alternative platforms soon enough to offset the anticompetitive harm resulting from this merger. As Dr. Willig (whose opinion Dr. Katz is bound by) admitted, he is unaware of any non-Illumina NGS sequencer that is currently available for sale. (PX7132 (Willig Dep. at 203)). [redacted] MCED test developers explained that they need and rely on Illumina NGS as their only NGS option. (CCFF, V(D)(2)). The overwhelming weight of the evidence also shows that any potential entry will not be likely, timely, or sufficient to offset the competitive harm of this transaction. (CCFF, VIII(B)). Therefore, this Court should disregard the proposed finding.

2052. [redacted]

[redacted]

Response to Finding No. 2052

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]

[redacted]

[redacted]

[redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents' proposed finding is also inherently speculative and against the weight of the evidence. Dr. Katz's theoretical assertion is unsupported by the market reality and can be explained by a multitude of factors. Respondents declined to ask a single MCED witness at trial to explain their understanding for the reasons that investors continue to invest in technology dependent on Illumina. Respondents also did not call any MCED investor at trial to explain their investment rationale. Dr. Katz also admitted that he was unaware of any conversations between Dr. Willig and any investor in an MCED company. (PX7145 (Katz Dep. at 140-141)). Indeed, to the contrary, several MCED witnesses expressed concern regarding the effect of this transaction on their ability to attract continued investment. [redacted]; PX7042 (Gao (Singlera) IHT at 130) ("Q: So Singlera will have a tougher time getting investment in the future? A: Uh-Huh. You know, because if we are relying on Illumina to provide the machine and the reagent, and then we are at the mercy of the pricing structure of Illumina. And Illumina can jack up the price of reagent or machine, you know, and then we will not be able to compete. And Illumina has no incentive to faithfully negotiate with anyone, not only Singlera, on how their machine will be used or priced. Q: Have any investors expressed this concern to Singlera? A: Many. Indeed, a lot of investor won't invest is because they feel even – their perception is that Illumina is so dominant, if Illumina is getting into the field, you better not get into it.")).

There are also multiple alternative explanations for MCED investment. Dr. Katz, however, admitted that he did not consider how these alternative factored into investors'

decision. (PX7145 (Katz Dep. at 140-141)).

2053.

Response to Finding No. 2053

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and

the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

Respondents present no factual evidence—not even self-serving testimony from their executives—to establish the assumptions underlying their expert's reasoning. [redacted] . Moreover, Respondents elicited no evidence that Illumina was "willing[] to pay such a large sum for Grail" because it "expect[ed] its ability to raise prices substantially in the future will be constrained." (Resp. Post-Trial Brief at 129-30.) And they provide no factual support for the assumption that "Illumina would be able to extract most of the returns from GRAIL's commercialized sales of NGS -based cancer screening tests." Resp. Post-Trial Brief at 129. [redacted]

[redacted]

The overwhelming record evidence contradicts Respondents' theory. Despite Respondents' characterization that their theory posits "real world facts," Resp. Post-Trial Brief 130, they offer none.

[redacted]

2054. Bargaining. Prof. Scott Morton's analysis of the impact of the proposed acquisition through the economic theory of bargaining or negotiation is flawed and fails to establish that the proposed transaction would substantially lessen competition. (RX3871 (Willig Expert Report) ¶ 8; RX6004 (Katz Trial Dep. at 53–58).)

Response to Finding No. 2054

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz

Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

[redacted]

[redacted]

2055. Prof. Scott Morton's bargaining example is based on a model that is unrelated to the key characteristics of the market that she and Complaint Counsel otherwise assume. (RX3871 (Willig Expert Report) ¶ 8; RX6004 (Katz Trial Dep at 54–56).)

Response to Finding No. 2055

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023). Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to

Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

[redacted]

[redacted]

2056. Even more striking is the fact that Prof. Scott Morton's conclusions within her own analytic frame are completely reversed with the addition of only one additional element—namely the availability of either an alternative upstream source or an ex ante supply agreement offer. (RX3871 (Willig Expert Report) ¶ 8; RX6004 (Katz Trial Dep at 56–58).)

Response to Finding No. 2056

Complaint Counsel objects to Respondents' proposed finding to the extent it endorses the biased and inherently unreliable opinion testimony of Dr. Katz. Dr. Katz normally spends approximately three to four hundred hours preparing for an expert report in a matter. (RX6004 (Katz Trial Dep. at 135-136)). Here, Dr. Katz only billed forty to fifty hours. (RX6004 (Katz Trial Dep. at 137)). In total, Dr. Katz allegedly considered over 6,533 pages of material in approximately forth to fifty hours. (RX6004 (Katz Trial Dep. at 137-141)). In effect, this means that he spent approximately less than half a minute per page in reviewing the materials listed on his materials considered list. (PX6105 (Katz Expert Report) at 017-023**).** Given his cursory review of the record, his opinion in this case is inherently unreliable and should be disregarded. Moreover, Dr. Katz violated this Court's order to confine his testimony to Dr. Willig's report and the basis for his opinion contained therein. (Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, 4 ("The substitute expert witness' trial testimony shall be limited to the opinions, bases or reasons therefor, and the data or other information considered or relied upon by Dr. Willig, as set forth in Dr. Willig's expert witness report."); [redacted]

[redacted]

[redacted]) Given the unreliable nature of Dr. Katz's opinion as well as Respondents' complete disregard of this Court's order, Dr. Katz's opinion should be disregarded.

[redacted]

E. Complaint Counsel's Experts

1. **Fiona Scott Morton**

a. Background

2057. Dr. Fiona Scott Morton is a Professor of Economics at Yale University and a researcher in the field of empirical industrial organization. (PX6090 (Scott Morton Expert Report) ¶¶ 1, 6.)

Response to Finding No. 2057

Complaint Counsel has no specific response to this proposed finding.

2058. [redacted]

Response to Finding No. 2058

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[redacted]

2059. [redacted]

Response to Finding No. 2059

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2060. [redacted]

Response to Finding No. 2060

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2061. [redacted]

Response to Finding No. 2061

[redacted]

[redacted]

2062. [redacted]

Response to Finding No. 2062

[redacted]

[redacted]

2063. [redacted]

Response to Finding No. 2063

[redacted]

a. Opinions

2064. [redacted]

Response to Finding No. 2064

[redacted]

2065. [redacted]

Response to Finding No. 2065

[redacted]

2065.1 [redacted]

Response to Finding No. 2065.1

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2065.2 [redacted]

Response to Finding No. 2065.2

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2065.3 [redacted]

Response to Finding No. 2065.3

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2065.4 [redacted]

Response to Finding No. 2065.4

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2065.5 [redacted]

Response to Finding No. 2065.5

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2066. [redacted]

Response to Finding No. 2066

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2066.1 [redacted]

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2066.2 [redacted]

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2066.3 [redacted]

Response to Finding No. 2066.3

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2066.4 [redacted]

Response to Finding No. 2066.4

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2066.5 [redacted]

Response to Finding No. 2066.5

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2066.6 [redacted]

Response to Finding No. 2066.6

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2067. [redacted]

Response to Finding No. 2067

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2067.1 [redacted]

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Response to Finding No. 2067.1

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2067.2 [redacted]

Response to Finding No. 2067.2

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2068. [redacted]

Response to Finding No. 2068

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2068.1 [redacted]

Response to Finding No. 2068.1

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2068.2 [redacted]

Response to Finding No. 2068.2

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2069. [redacted]

Response to Finding No. 2069

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2069.1 [redacted]

Response to Finding No. 2069.1

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2069.2 [redacted]

Response to Finding No. 2069.2

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2070. [redacted]

Response to Finding No. 2070

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2071. [redacted]

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2073. [redacted]

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2076. [redacted]

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2077. [redacted]

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2078. [redacted]

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2079. [redacted]

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2080. [redacted]

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2081. [redacted]

Response to Finding No. 2081

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2082. [redacted]

Response to Finding No. 2082

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2083. [redacted]

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2083.1 [redacted]

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2083.2 [redacted]

Response to Finding No. 2083.2

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2083.3 [redacted]

Response to Finding No. 2083.3

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2083.4 [redacted]

Response to Finding No. 2083.4

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2083.5 [redacted]

Response to Finding No. 2083.5

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2083.6 [redacted]

Response to Finding No. 2083.6

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2084. [redacted]

Response to Finding No. 2084

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2085. [redacted]

Response to Finding No. 2085

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2086. [redacted]

Response to Finding No. 2086

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2087. [redacted]

Response to Finding No. 2087

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2088. [redacted]

Response to Finding No. 2088

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2089. [redacted]

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Response to Finding No. 2089

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2090. [redacted]

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2091. [redacted]

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2093. [redacted]

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2094. [redacted]

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2095. [redacted]

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2097. [redacted]

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2099. [redacted]

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2099.3 [redacted]

Response to Finding No. 2099.3

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Response to Finding No. 2099.4

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2099.5 [redacted]

Response to Finding No. 2099.5

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Response to Finding No. 2099.6

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2099.8 [redacted]

Response to Finding No. 2099.8

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2099.9 [redacted]

Response to Finding No. 2099.9

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2100. [redacted]

Response to Finding No. 2100

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2101. [redacted]

Response to Finding No. 2101

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2101.1 [redacted]

Response to Finding No. 2101.1

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2101.2 [redacted]

Response to Finding No. 2101.2

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2101.3 [redacted]

Response to Finding No. 2101.3

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2102. [redacted]

Response to Finding No. 2102

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2102.1 [redacted]

Response to Finding No. 2102.1

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2102.2 [redacted]

Response to Finding No. 2102.2

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2103. [redacted]

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2104. [redacted]

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2105. [redacted]

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2106. [redacted]

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2106.2 [redacted]

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2106.3 [redacted]

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2106.4 [redacted]

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2107. [redacted]

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2108. [redacted]

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2109. [redacted]

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2111. [redacted]

Response to Finding No. 2111

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2111.1 [redacted]

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2112. [redacted]

Response to Finding No. 2112

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2113. [redacted]

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2114. [redacted]

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2118. [redacted]

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2120. [redacted]

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2120.2 [redacted]

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2120.3 [redacted]

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2120.4 [redacted]

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2121. [redacted]

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2122. [redacted]

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2124. [redacted]

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2126. [redacted]

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2127. [redacted]

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2127.1 [redacted]

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2127.2 [redacted]

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2128. [redacted]

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2129. [redacted]

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2130. [redacted]

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2131. [redacted]

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2132. [redacted]

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2132.1 [redacted]

Response to Finding No. 2132.1

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2132.2 [redacted]

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2132.3 [redacted]

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2132.4 [redacted]

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2132.5 [redacted]

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2132.7 [redacted]

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2132.8 [redacted]

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2132.9 [redacted]

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2132.10 [redacted]

Response to Finding No. 2132.10

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2133. [redacted]

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2134. [redacted]

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2135. [redacted]

Response to Finding No. 2135

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2136. [redacted]

Response to Finding No. 2136

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[redacted]

2136.1 Dr. Scott Morton repeatedly weighs the evidence in the course of offering her opinions here. (RX3852 (Scott Morton Dep. at 193, 212).) [redacted] She also takes at face value the FTC's arguments and disregards efficiencies sworn to by Illumina fact witnesses. (RX3852 (Scott Morton, Dep. at 242) ("Q. . . . No one has shared with you any deposition testimony concerning supply chain and operational efficiencies expected because of the transaction; correct? A. I asked for everything important. Therefore, there isn't anything of importance for my report that falls in the category you are talking about, or I would've seen it.").)

Response to Finding No. 2136.1

[redacted]

[redacted]

[redacted]

2. **Amol Navathe**

a. Background

2137. [redacted]

Response to Finding No. 2137

[redacted]

2138. Dr. Navathe's research focuses on health economics. (PX7139 (Navathe Trial Dep. at 9.)

Response to Finding No. 2138

[redacted]

[redacted]

b. Opinions

2139. Acceleration of Reimbursement. [redacted]

Response to Finding No. 2139

[redacted]

2140. Dr. Navathe is not an expert on FDA evaluation of MCED tests, including Galleri. (PX7139 (Navathe Trial Dep. at 97–99.)

Response to Finding No. 2140

[redacted]

2141. Dr. Navathe lacks expertise on subjects relevant to concluding that the transaction will not accelerate payer reimbursement and approval of Galleri. (PX7139 (Navathe Trial Dep. at 98–102.)

Response to Finding No. 2141

This proposed finding is inaccurate. There is ample evidence that Dr. Navathe has experience and expertise regarding the evidentiary standards the FDA considers, and the types of evidence public and private payers consider. Dr. Navathe has extensive experience regarding payer reimbursement. Dr. Navathe is a commissioner of the Medicare Payment Advisory Commission (MedPAC) and has served in this role since 2018. (PX7139 (Navathe Trial Dep. at 14)). MedPAC is a nonpartisan agency of the U.S. Congress that works directly with the Senate Finance Committee, the House Ways and Means Committee, and the House Energy and Commerce Committee on all aspects of Medicare policy, providing neutral recommendations from a political perspective based on data analysis and the best available evidence to Congress as well as providing recommendations directly to the CMS. (PX7139 (Navathe Trial Dep. at 14)). MedPac advises broadly on Medicare payment policies that may influence Medicare reimbursement decisions. (RX3853 (Navathe) Dep. at 75). Additionally, Dr. Navathe has consulting experience related to seeking reimbursement for medical products. (PX7139 (Navathe Trial Dep at 15)). Dr. Navathe "worked extensively with manufacturers to help develop market access plans and strategies" to approach payers, including private payers, "to secure reimbursement" as well as to "structure a variety of different types of value-based or outcome-based or risk-based types of contracts." (PX7139 (Navathe Trial Dep. at 16)).

Dr. Navathe's academic research also involves healthcare reimbursement, some of which has been implemented with payers. For example, some of Dr. Navathe's research has related to value-based payment models, which are payments models involving the "final payment amount in reference to the value, in other words, in terms of the patient outcome, the quality, the patient experience or a number of other measures that are intended to assess the quality and the value of the service or product delivered." (PX7139 (Navathe Trial Dep. at 9-10)). Other research of Dr.

Navathe's has related to reimbursement for medical devices by public payers. (PX7139 (Navathe Trial Dep. at 10-11)). Specifically, Dr. Navathe's research has "examined the implications of the vast amounts of new types of data that have become available to algorithms, including detailed clinical data . . . that's available, for example, in an electronic health record, and the implications for devices that use machine learning algorithms to interpret this data" as well as providing input to clinicians regarding making healthcare decisions that ultimately affect patients. (PX7139 (Navathe Trial Dep. at 11-12)).

Dr. Navathe also has significant experience working with the FDA and evaluating the types of data the FDA uses to make decisions. (PX7139 (Navathe Trial Dep. at 16-17). Dr. Navathe was a senior program manager and medical officer at the Department of Health and Human Services in the Office of the Secretary from 2009 to 2011. In that work, Dr. Navathe testified that he "worked extensively with the FDA on the development and direct investment of the federal government in data infrastructure to support comparative effectiveness and to also support real-world evidence research that could be utilized by the FDA." (PX7139 (Navathe Trial Dep. at 17)). Further, Dr. Navathe "worked collaboratively with the FDA on a project called the Mini-Sentinel project" in which HHS worked directly with private payers to set up a multipayer claims database to support the type of post-market surveillance after FDA approval of medical products. (PX7139 (Navathe Trial Dep. at 17)). Dr. Navathe's work at HHS related to the evidentiary requirements for premarket approval from the FDA. (PX7139 (Navathe Trial Dep. at 17-18)). Additionally, Dr Navathe's research has considered the type of evidence that the FDA may consider in approving medical diagnostics. (PX7139 (Navathe Trial Dep. at 12)).

The subjects of the types of evidence both the FDA and payers consider, and the reimbursement structures payers use is, of course, relevant to an opinion about arguments

Respondents' experts have made that the transaction will accelerate payer reimbursement and approval of Galleri. This proposed finding is, therefore, inaccurate. Therefore, this Court should disregard the proposed finding.

2142. Dr. Navathe does not have any experience in obtaining FDA approval for any product, including building and supervising a team seeking FDA approval or analyzing a company's capability to get FDA approval. (PX7139 (Navathe Trial Dep. at 101.)

Response to Finding No. 2142

This proposed finding is inaccurate and misleading. It is inaccurate to state that Dr. Navathe does not have "any experience in obtaining FDA approval for any product." Dr Navathe's work at HHS related to the evidentiary requirements for premarket approval from the FDA. (PX7139 (Navathe Trial Dep. at 17-18)). Additionally, Dr Navathe's research has considered the type of evidence that the FDA may consider in approving medical diagnostics. (PX7139 (Navathe Trial Dep. at 12)). The remainder of this proposed finding is misleading insofar as Respondents are using this lack of specific expertise to claim Dr. Navathe has no relevant expertise to evaluating the opinions of Respondents' experts. As explained in Complaint Counsel's response to Respondents Proposed Finding Number 2141, above, Dr. Navathe's expertise regarding the types of evidence both payors and the FDA consider is highly relevant to assessing the acceleration claims made by Respondents' experts. Therefore, this Court should disregard the proposed finding.

2143. Dr. Navathe does not have any experience in seeking premarket authorization from the FDA for any product. (PX7139 (Navathe Trial Dep. at 101.)

Response to Finding No. 2143

This proposed finding is misleading. Dr Navathe's work at HHS related to the evidentiary requirements for premarket approval from the FDA. (PX7139 (Navathe Trial Dep. at 17-18)). Additionally, Dr Navathe's research has considered the type of evidence that the FDA

may consider in approving medical diagnostics. (PX7139 (Navathe Trial Dep. at 12)). This proposed finding is misleading insofar as Respondents are using this lack of specific expertise to claim Dr. Navathe has no relevant expertise to evaluating the opinions of Respondents' experts. As explained in Complaint Counsel's response to Respondents Proposed Finding Number 2141, above, Dr. Navathe's expertise regarding the types of evidence both payers and the FDA consider is highly relevant to assessing the acceleration claims made by Respondents' experts. Therefore, this Court should disregard the proposed finding.

2144. Dr. Navathe has never built a team to seek payor coverage for a medical diagnostic. (PX7139 (Navathe Trial Dep. at 106.)

Response to Finding No. 2144

This proposed finding is misleading. Dr. Navathe has extensive experience with payors and reimbursement in the United States. Dr. Navathe is a commissioner of the Medicare Payment Advisory Commission (MedPAC) and has served in this role since 2018. (PX7139 (Navathe Trial Dep. at 14)). MedPac advises on Medicare payment policies that influence Medicare reimbursement decisions. (RX3853 (Navathe) Dep. at 75). Additionally, Dr. Navathe has consulting experience where he "worked extensively with manufacturers to help develop market access plans and strategies" toward seeking reimbursement for medical products. (PX7139 (Navathe Trial Dep at 15-16)). Dr. Navathe's academic research also involves healthcare reimbursement, some of which has been implemented with payors. (PX7139 (Navathe Trial Dep. at 9-12)). This proposed finding is misleading insofar as Respondents are using this lack of specific expertise to claim Dr. Navathe has no relevant expertise to evaluating the opinions of Respondents' experts. As explained in Complaint Counsel's response to Respondents Proposed Finding Number 2141, above, Dr. Navathe's expertise regarding the types of evidence both payors and the FDA consider is highly relevant to assessing the acceleration

claims made by Respondents' experts. Therefore, this Court should disregard the proposed finding.

2145. Dr. Navathe has never supervised a team working on seeking payor coverage for a medical diagnostic. (PX7139 (Navathe Trial Dep. at 106.)

Response to Finding No. 2145

This proposed finding is misleading. Dr. Navathe has extensive experience with payors and reimbursement in the United States. Dr. Navathe is a commissioner of the Medicare Payment Advisory Commission (MedPAC) and has served in this role since 2018. (PX7139 (Navathe Trial Dep. at 14)). MedPac advises on Medicare payment policies that influence Medicare reimbursement decisions. (RX3853 (Navathe) Dep. at 75). Additionally, Dr. Navathe has consulting experience where he "worked extensively with manufacturers to help develop market access plans and strategies" toward seeking reimbursement for medical products. (PX7139 (Navathe Trial Dep at 15-16)). Dr. Navathe's academic research also involves healthcare reimbursement, some of which has been implemented with payors. (PX7139 (Navathe Trial Dep. at 9-12)). This proposed finding is misleading insofar as Respondents are using this lack of specific expertise to claim Dr. Navathe has no relevant expertise to evaluating the opinions of Respondents' experts. As explained in Complaint Counsel's response to Respondents Proposed Finding Number 2141, above, Dr. Navathe's expertise regarding the types of evidence both payors and the FDA consider is highly relevant to assessing the acceleration claims made by Respondents' experts. Therefore, this Court should disregard the proposed finding.

2146. Dr. Navathe has never helped a manufacturer of a medical diagnostic test generate evidence to obtain payor coverage. (PX7139 (Navathe Trial Dep. at 106.)

Response to Finding No. 2146

This proposed finding is misleading. Dr. Navathe has extensive experience with payers

and reimbursement in the United States. Dr. Navathe is a commissioner of the Medicare Payment Advisory Commission (MedPAC) and has served in this role since 2018. (PX7139 (Navathe Trial Dep. at 14)). MedPac advises on Medicare payment policies that influence Medicare reimbursement decisions. (RX3853 (Navathe) Dep. at 75). Additionally, Dr. Navathe has consulting experience where he "worked extensively with manufacturers to help develop market access plans and strategies" toward seeking reimbursement for medical products. (PX7139 (Navathe Trial Dep at 15-16)). Dr. Navathe's academic research also involves healthcare reimbursement, some of which has been implemented with payors. (PX7139 (Navathe Trial Dep. at 9-12)). This proposed finding is misleading insofar as Respondents are using this lack of specific expertise to claim Dr. Navathe has no relevant expertise to evaluating the opinions of Respondents' experts. As explained in Complaint Counsel's response to Respondents Proposed Finding Number 2141, above, Dr. Navathe's expertise regarding the types of evidence both payors and the FDA consider is highly relevant to assessing the acceleration claims made by Respondents' experts. Therefore, this Court should disregard the proposed finding.

2147. Dr. Navathe has never analyzed a company's capability to get payor coverage for a medical diagnostic test. (PX7139 (Navathe Trial Dep. at 106–07.)

Response to Finding No. 2147

This proposed finding is misleading. Dr. Navathe has extensive experience with payors and reimbursement in the United States. Dr. Navathe is a commissioner of the Medicare Payment Advisory Commission (MedPAC) and has served in this role since 2018. (PX7139 (Navathe Trial Dep. at 14)). MedPac advises on Medicare payment policies that influence Medicare reimbursement decisions. (RX3853 (Navathe) Dep. at 75). Additionally, Dr. Navathe has consulting experience where he "worked extensively with manufacturers to help develop

market access plans and strategies" toward seeking reimbursement for medical products. (PX7139 (Navathe Trial Dep at 15-16)). Dr. Navathe's academic research also involves healthcare reimbursement, some of which has been implemented with payors. (PX7139 (Navathe Trial Dep. at 9-12)). This proposed finding is misleading insofar as Respondents are using this lack of specific expertise to claim Dr. Navathe has no relevant expertise to evaluating the opinions of Respondents' experts. As explained in Complaint Counsel's response to Respondents Proposed Finding Number 2141, above, Dr. Navathe's expertise regarding the types of evidence payers consider is highly relevant to assessing the acceleration claims made by Respondents' experts. Therefore, this Court should disregard the proposed finding.

2148. Dr. Navathe does not have any experience with coverage decisions for medical diagnostics, including MCED tests. (PX7139 (Navathe Trial Dep. at 107)

Response to Finding No. 2148

[redacted]

[redacted]

2149. [redacted]

Response to Finding No. 2149

[redacted]

[redacted]

2150. Dr. Navathe agrees that to commercialize Galleri at scale so that it becomes widely available to large numbers of Americans, Galleri will need to achieve FDA approval, Medicare coverage and private payer coverage. (PX7139 (Navathe Trial Dep. at 118.)

Response to Finding No. 2150

[redacted] Otherwise, Complaint Counsel does not disagree with this proposed finding.

2151. Dr. Navathe admits facts establishing that GRAIL will have difficulty obtaining payer coverage and approval without the benefit of Illumina's payer experience.

Response to Finding No. 2151

The proposed finding is unsupported because no evidence is cited for this proposed finding. This proposed finding is also vague because Respondents do not identify any "facts" Dr. Navathe purportedly admits. Therefore, this Court should disregard the proposed finding.

2152. [redacted]

Response to Finding No. 2152

[redacted]

[redacted]

2153. [redacted]

Response to Finding No. 2153

[redacted]

[redacted]

Response to Finding No. 2154

[redacted]

2155. [redacted]

[redacted]

Response to Finding No. 2155

Complaint Counsel agrees with the first part of this proposed finding that "the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 is a potential legislation that may provide coverage of MCED test[s]." [redacted]

2156. [redacted]

Response to Finding No. 2156

[redacted]

2157. [redacted]

Response to Finding No. 2157

[redacted]

2158. [redacted]

Response to Finding No. 2158

[redacted]

[redacted]

[redacted]

2159. [redacted]

Response to Finding No. 2159

[redacted]

[redacted]

2160. [redacted]

Response to Finding No. 2160

[redacted]

2161. [redacted]

Response to Finding No. 2161

[redacted]

[redacted]

2162. Dr. Navathe testified to facts showing that, absent the transaction, there is no guarantee that GRAIL will obtain payer coverage of Galleri at the same time or earlier than it would with completion of the transaction.

Response to Finding No. 2162

The proposed finding is unsupported because no evidence is cited for this proposed finding. This proposed finding is also vague because Respondents do not identify any "facts" Dr. Navathe purportedly admits. This Court should disregard this proposed finding.

2163. [redacted]

Response to Finding No. 2163

[redacted]

[redacted]

2164. [redacted]

Response to Finding No. 2164

[redacted]

[redacted]

2165. [redacted]

Response to Finding No. 2165

[redacted]

[redacted]

2166. [redacted]

Response to Finding No. 2166

[redacted]

[redacted]

2167. [redacted]

Response to Finding No. 2167

[redacted]

[redacted]

2168. [redacted]

Response to Finding No. 2168

[redacted]

[redacted]

2169. [redacted]

Response to Finding No. 2169

[redacted]

[redacted]

[redacted]

2170. Dr. Navathe did not reach independent conclusions about whether the transaction will accelerate approval of Galleri.

Response to Finding No. 2170

The proposed finding is unsupported because no evidence is cited for this proposed finding. This proposed finding is also vague because Respondents do not identify any "conclusions" nor specify whose "approval" they are referring to. This Court should disregard this proposed finding.

2171. [redacted]

Response to Finding No. 2171

[redacted]

[redacted]

2172. [redacted]

Response to Finding No. 2172

[redacted]

[redacted]

2173. [redacted]

Response to Finding No. 2173

[redacted]

2174. [redacted]

Response to Finding No. 2174

[redacted]

2175. [redacted]

Response to Finding No. 2175

[redacted]

2176. [redacted]

Response to Finding No. 2176

[redacted]

[redacted]

2176.1 [redacted]

Response to Finding No. 2176.1

[redacted]

[redacted]

2177. [redacted]

Response to Finding No. 2177

[redacted]

[redacted]

[redacted]

[redacted]

2178. Value of Lives Saved. Dr. Navathe asserts that Dr. Carlton's analysis of the value of lives saved from the purported acceleration of Galleri is flawed and unreliable.

Response to Finding No. 2178

Complaint Counsel does not disagree with this proposed finding but notes that it is unsupported.

2179. [redacted] holding all other factors constant, if more Galleri tests are conducted, more cancers will be found at earlier stages, (PX7139 (Navathe Trial Dep. at 136); if FDA approval for Galleri, Medicare reimbursement for Galleri and private payer coverage for Galleri were accelerated such that the use of Galleri at scale in the United States were accelerated, more patients would have access to Galleri than if those things didn't occur. (PX7139 (Navathe Trial Dep. at 136.)

Response to Finding No. 2179

[redacted]

2180. [redacted]

Response to Finding No. 2180

[redacted]

2181. Dr. Navathe claims that Dr. Carlton's use of the VSL methodology is not used as a professional standard in health economics, but Dr. Navathe admits that the Department of Health and Human Services Guidelines for Regulatory Impact Analysis approach for valuing mortality risk reductions includes the use of value per statistical life. (PX7139 (Navathe Trial Dep. at 143.)

Response to Finding No. 2181

[redacted]

[redacted]

[redacted]

2182. Dr. Navathe lacks key information concerning scholarly usage of the VSL methodology.

Response to Finding No. 2182

This proposed finding should be disregarded because it is completely unsupported by evidence. The proposed finding is also fatally vague because it does not identify what relevant "key information" regarding the scholarly usage of VSL Dr. Navathe purportedly lacked, nor even identify what "scholarly usage" is being referred to. Therefore, this Court should disregard the proposed finding.

2183. Dr. Navathe was not aware of the Department of Health and Human Services guideline on the use of value per statistical life for valuing mortality risk reductions at the time he drafted his report. (PX7139 (Navathe Trial Dep. at 145.)

Response to Finding No. 2183

[redacted]

[redacted]

[redacted]

2184. Dr. Navathe was not aware of the Food and Drug Administration's Mammography Quality Standards Act: Amendments to Part 900 Regulations that used the value per statistical life approach to value reduced mortality as well as breast cancer treatment costs at the time that he drafted his report. (PX7139 (Navathe Trial Dep. at 146–49.)

Response to Finding No. 2184

[redacted]

[redacted]

[redacted]

2185. [redacted]

Response to Finding No. 2185

[redacted]

[redacted]

3. **Dov Rothman**

a. Background

2186. Dr. Dov Rothman is the Managing Principal of Analysis Group, Inc., and has previously provided expert testimony on matters involving commercial health insurers, hospital, physicians and pharmaceuticals. (PX7140 (Rothman Trial Dep. at 7, 9.)

Response to Finding No. 2186

Complaint Counsel has no specific response to this proposed finding.

2187. Dr. Rothman is not an expert in FDA approval, (PX7140 (Rothman Trial Dep. at 42–43); payer reimbursement, (PX7140 (Rothman Trial Dep. at 45); medical technology risk-sharing agreements, (PX7140 (Rothman Trial Dep. at 45–46); medical device collaborations, (PX7140 (Rothman Trial Dep. at 46);

Response to Finding No. 2187

[redacted]

2188. Dr. Rothman does not have any prior experience analyzing the efficiencies of vertical mergers. (PX7140 (Rothman Trial Dep. at 42.)

Response to Finding No. 2188

The proposed finding is misleading, mischaracterizes Dr. Rothman's testimony, and should be disregarded by this Court. Dr. Rothman does not testify that he "does not have any prior experience analyzing efficiencies of vertical mergers." In the cited portion of Dr. Rothman's trial deposition testimony, he agreed that he has not "testified in any merger litigation where the transaction being challenged was a vertical acquisition[.]" (PX7140 (Rothman Trial Dep. at 42)). This clearly does not demonstrate that he "does not have any prior experience analyzing" efficiencies in vertical mergers, but rather that he has not "testified in any . . . vertical acquisition" merger litigations. (PX7140 (Rothman Trial Dep. at 42)). Furthermore, by

inferring that Dr. Rothman's experience with vertical transactions is limited to instances in which he gave testimony would omit instances where Dr. Rothman's work was bound by confidentiality agreements. Respondents' proposed finding is incorrect, misleading on its face, and should be disregarded by this Court.

b. Opinions

2189. Efficiencies. Dr. Rothman asserts that Respondents' experts have not adequately substantiated that the transaction will accelerate FDA and payer approval of Galleri or create research and development and supply chain and operational efficiencies.

Response to Finding No. 2189

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order. Therefore, this Court should disregard the proposed finding.

2190. Dr. Rothman opines that efficiencies must be able to be verified by reasonable means and relied only on the FTC's and DOJ's Horizontal Merger Guidelines and Vertical Merger Guidelines as support, (PX7140 (Rothman Trial Dep. at 54–57), but Dr. Rothman acknowledges issues attendant to his asserted efficiencies verification standard.

Response to Finding No. 2190

The proposed finding is incomplete. Dr. Rothman opined that, as Respondents put it and consistent with the Horizontal Merger Guidelines, "efficiencies must be able to be verified by reasonable means." (*See, e.g.*, PX7140 (Rothman Trial Dep. at 15)). But Dr. Rothman also testified, consistent with the Guidelines, that "[a] cognizable efficiency is an efficiency . . . that's merger specific, and that's not the result of an anticompetitive reduction in output." (PX7140 (Rothman Trial Dep. at 15); *see also* Horizontal Merger Guidelines § 10). Respondents'

proposed finding is incomplete, misrepresentative, and should be disregarded by this Court.

The proposed finding is also vague and confusing. As an initial matter, Respondents fail to define the term "issues attendant." Moreover, Respondents claim that Dr. Rothman "relied only on" the Horizontal and Vertical Merger Guidelines "as support." But Respondents do not indicate what they claim is supported "only" by the Horizontal and Vertical Merger Guidelines. To the extent Respondents suggest Dr. Rothman, in forming his opinions "relied only on the . . . Horizontal . . . and Vertical Merger Guidelines," the proposed finding is misleading and incorrect, and should be disregarded by this Court. [redacted]

The final clause of the proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order.

> 2190.1 Dr. Rothman admits that neither the Vertical Merger Guidelines or the Horizontal Merger Guidelines use the phrase "reasonable means". (PX7140 (Rothman Trial Dep. at 58–59, 64).

Response to Finding No. 2190.1

The proposed finding is incorrect, misleading, and should be rejected by this Court. Dr. Rothman agreed that, when they were in effect, the Vertical Merger Guidelines "[did not] even use the phrase reasonable means." (PX7140 (Rothman Trial Dep. at 58)). But he does not say

the same for the Horizontal Merger Guidelines. (*See* generally PX7140 (Rothman Trial Dep. at 59-59, 64)). Dr. Rothman testified that the Horizontal Merger Guidelines "don't contain a definition of 'reasonable means,'" but this does not support Respondents' factual proposition. In fact, the Horizontal Merger Guidelines clearly "use the phrase 'reasonable means.'" (Horizontal Merger Guidelines § 10) ("it is incumbent upon the merging firms to substantiate efficiency claims so that the Agencies can verify by *reasonable means*") (emphasis added); *id*. ("Efficiency claims will not be considered if they are vague, speculative, or otherwise cannot be verified by *reasonable means*.") (emphasis added). Moreover, when they were in effect, the Vertical Merger Guidelines incorporated the Horizontal Merger Guidelines by reference, thereby, at least imlicitly, "us[ing] the phrase 'reasonable means.'" (*See* Vertical Merger Guidelines § 6) ("The Agencies evaluate efficiency claims by the parties using the approach set forth in Section 10 of the Horizontal Merger Guidelines, as elaborated here."). Respondents' proposed finding is incorrect, mischaracterizes Dr. Rothman's testimony, and should be rejected by this Court.

2190.2 Dr. Rothman concedes that the FTC withdrew the Vertical Merger Guidelines after Dr. Rothman's report was submitted. (PX7140 (Rothman Trial Dep. at 60.)

Response to Finding No. 2190.2

Complaint Counsel has no specific response to this proposed finding.

2190.3 Dr. Rothman agrees that the Vertical Merger Guidelines do not dictate to a court how to assess the efficiencies of a vertical merger. (PX7140 (Rothman Trial Dep. at 62.)

Response to Finding No. 2190.3

Complaint Counsel has no specific response to this proposed finding.

2190.4 Dr. Rothman admits that verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency. (PX7140 (Rothman Trial Dep. at 67.)

Response to Finding No. 2190.4

The proposed finding is incorrect. Nowhere in his testimony does Dr. Rothman "admit" that "verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency." He agrees, however, that the "Merger Guidelines," do say that. (PX7140 (Rothman Trial Dep. at 66) ("Q. And the Merger Guidelines don't say that the magnitude can only be verified by reasonable means if that magnitude is defined at the level of a specific dollar amount, do they? A. No.")). But he does not provide the admission listed in Respondents' proposed finding—i.e., Dr. Rothman's testimony only concerns what the "Merger Guidelines" say. The proposed finding is therefore incorrect, misleading, and should be disregarded by this Court.

> 2190.5 Dr. Rothman concedes that the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not require that costs to achieve an efficiency have to be specified by a specific dollar amount. (PX7140 (Rothman Trial Dep. at 67.)

Response to Finding No. 2190.5

The proposed finding is vague and unclear. Respondents do not define the phrase "be specified by a specific dollar amount," leaving it unclear exactly what Respondents' proposed finding is meant to communicate. The proposed finding is misleading—largely because it is unclear. Dr. Rothman did not testify that the Guidelines "do not require that costs to achieve and efficiency have to be specified by a specific dollar amount." In his testimony, Dr. Rothman agreed that the "Merger Guidelines" do not "require costs associated with a claimed efficiency to be established with any given level of dollar specificity." (PX7140 (Rothman Trial Dep. at 67)). It is unclear from the finding whether "any given level of dollar specificity" is the same as "specified by a specific dollar amount."

> 2190.6 Dr. Rothman agrees that the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not provide a precise timeline for when parties need to establish an efficiency in order for the efficiency to be cognizable. (PX7140 (Rothman Trial Dep. at 67.)

Response to Finding No. 2190.6

The proposed finding is vague and should be disregarded by this Court. The proposed finding is vague because the phrase "a precise timeline for when parties need to establish an efficiency" is ambiguous, at best. It is unclear if, by that phrase, Respondents mean when an efficiency must be "establish[ed]" as a matter of proof in litigation, or if Respondents mean when the actual efficiency would be achieved.

If Respondents mean the former, as it seems they do from the proposed finding's phrasing, then this proposed finding is incorrect and misleading. Dr. Rothman did not testify about "when parties need to establish an efficiency." He testified about "how precisely parties need to establish the timing of an efficiency"—i.e., what Respondents must do to show when an efficiency will be achieved. (PX7140 (Rothman Trial Dep. at 67)). Therefore, this Court should disregard the proposed finding.

2190.7 [redacted]

Response to Finding No. 2190.7

Complaint Counsel has no specific response to this proposed finding.

2191. Dr. Rothman is not offering an opinion as to whether Respondents' support for the asserted efficiencies satisfies the relevant legal burden of proof. (PX7140 (Rothman Trial Dep. at 62–63); [redacted]

Response to Finding No. 2191

[redacted]

2192. [redacted]

Response to Finding No. 2192

[redacted]

2193. Acceleration of Galleri. Dr. Rothman asserts that Respondents' experts have not adequately substantiated that the transaction will accelerate FDA and payer approval of the Galleri test.

Response to Finding No. 2193

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention

of this Court's Order. Therefore, this Court should disregard the proposed finding.

2194. Dr. Rothman lacks expertise on subjects relevant to determining whether the transaction will accelerate FDA and payer approval of Galleri.

Response to Finding No. 2194

The proposed finding is uncited, improper, and should be rejected by this Court. The proposed finding is unsupported because no evidence is cited for the factual proposition. This Court has ordered that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Findings at 2). Here, Respondents' improperly fail to provide any specific reference in support of their proposed finding, in direct contravention of this Court's Order. Therefore, this Court should disregard the proposed finding.

2194.1 Dr. Rothman is not an expert in FDA approval. (PX7140 (Rothman Trial Dep. at 42–43.)

Response to Finding No. 2194.1

[redacted]

[redacted]

The proposed finding is further misleading to the extent it implies that Dr. Rothman must be an expert in any of the listed areas to formulate and express an appropriate opinion regarding the efficiencies claimed by Respondents' experts. Dr. Rothman does not hold himself out as having any particular expertise with respect to FDA approval, payer reimbursement, medical technology risk sharing agreements, medical device collaborations, [redacted] Rather, as he explained, Dr. Rothman is an expert in evaluating "competitive effects as well as efficiencies" of mergers, including the efficiencies Respondents claim here, which he has learned about throughout the case. (PX7140 (Rothman Trial Dep. at 9)). And though he does not have any pre-existing expertise related to the listed topics, he has relied on the factual record, other experts, and the testimony of witnesses who do have such expertise, and he has analyzed this information as it relates to the efficiencies claimed by Respondents' experts. (PX7140 (Rothman Trial Dep. at 13-14)). Therefore, this Court should disregard the proposed finding.

2194.2 Dr. Rothman is not an expert in payer reimbursement. (PX7140 (Rothman Trial Dep. at 45.)

Response to Finding No. 2194.2

[redacted]

[redacted]

The proposed finding is further misleading to the extent it implies that Dr. Rothman must be an expert in any of the listed areas to formulate and express an appropriate opinion regarding the efficiencies claimed by Respondents' experts. Dr. Rothman does not hold himself out as having any particular expertise with respect to FDA approval, payer reimbursement, medical technology risk sharing agreements, medical device collaborations, [redacted] Rather, as he explained, Dr. Rothman is an expert in evaluating "competitive effects as well as efficiencies," of mergers including the efficiencies

Respondents claim here, which he has learned about throughout the case. (PX7140 (Rothman Trial Dep. at 9)). And though he does not have any pre-existing expertise related to the listed topics, he has relied on the factual record, other experts, and the testimony of witnesses who do have such expertise, and he has analyzed this information as it relates to the efficiencies claimed by Respondents' experts. (PX7140 (Rothman Trial Dep. at 13-14)). Therefore, this Court should disregard the proposed finding.

2194.3 Dr. Rothman is not an expert in medical technology risk-sharing agreements. (Rothman, Tr. 45–46.)

Response to Finding No. 2194.3

[redacted]

[redacted]

The proposed finding is further misleading to the extent it implies that Dr. Rothman must be an expert in any of the listed areas to formulate and express an appropriate opinion regarding the efficiencies claimed by Respondents' experts. Dr. Rothman does not hold himself out as having any particular expertise with respect to FDA approval, payer reimbursement, medical technology risk sharing agreements, medical device collaborations, [redacted] Rather, as he explained, Dr. Rothman is an expert in evaluating "competitive effects as well as efficiencies," of mergers including the efficiencies Respondents claim here, which he has learned about throughout the case. (PX7140 (Rothman Trial Dep. at 9)). And though he does not have any pre-existing expertise related to the listed topics, he has relied on the factual record, other experts, and the testimony of witnesses who do have such expertise, and he has analyzed this information as it relates to the efficiencies claimed by Respondents' experts. (PX7140 (Rothman Trial Dep. at 13-14)).

The proposed finding is also vague. Respondents fail to define the term "medical technology risk-sharing agreements." Therefore, this Court should disregard the proposed finding.

2194.4 Dr. Rothman is not an expert in medical device evidence generating collaborations. (Rothman, Tr. 46.)

Response to Finding No. 2194.4

[redacted]

[redacted]

The proposed finding is further misleading to the extent it implies that Dr. Rothman must be an expert in any of the listed areas to formulate and express an appropriate opinion regarding the efficiencies claimed by Respondents' experts. Dr. Rothman does not hold himself out as having any particular expertise with respect to FDA approval, payer reimbursement, medical technology risk sharing agreements, medical device collaborations, [redacted] Rather, as he explained, Dr. Rothman is an expert in evaluating "competitive effects as well as efficiencies," of mergers including the efficiencies Respondents claim here, which he has learned about throughout the case. (PX7140 (Rothman

Trial Dep. at 9)). And though he does not have any pre-existing expertise related to the listed topics, he has relied on the factual record, other experts, and the testimony of witnesses who do have such expertise, and he has analyzed this information as it relates to the efficiencies claimed by Respondents' experts. (PX7140 (Rothman Trial Dep. at 13-14)).

The proposed finding is also vague. Respondents fail to define the term "medical device evidence generating collaborations." Therefore, this Court should disregard the proposed finding.

2194.5 [redacted]

Response to Finding No. 2194.5

[redacted]

[redacted]

The proposed finding is further misleading to the extent it implies that Dr. Rothman must be an expert in [redacted] to formulate and express an appropriate opinion regarding the efficiencies claimed by Respondents' experts. Dr. Rothman does not hold himself out as having any particular expertise with respect to [redacted] Rather, as he explained, Dr. Rothman is an expert in evaluating "competitive effects as well as efficiencies," of mergers including the efficiencies Respondents claim here, which he has learned about throughout the case. (PX7140 (Rothman Trial Dep. at 9)). And though he does not have any pre-existing expertise related to the listed topic, he has relied on the factual record, other experts, and the testimony of witnesses who do have such expertise, and he has analyzed this information as it relates to the efficiencies claimed by Respondents' experts. (PX7140 (Rothman Trial Dep. at 13-14)).

The proposed finding is also vague. Respondents fail to define the terms [redacted] Therefore, this Court should disregard the proposed finding.

2194.6 [redacted]

Response to Finding No. 2194.6

[redacted]

[redacted]

The proposed finding is further misleading to the extent it implies that Dr. Rothman must be an expert in [redacted] to formulate and express an appropriate opinion regarding the efficiencies claimed by Respondents' experts. Dr. Rothman does not hold himself out as having any particular expertise with respect to [redacted] Rather, as he explained, Dr. Rothman is an expert in evaluating "competitive effects as well as efficiencies," of mergers including the efficiencies Respondents claim here, which he has learned about throughout the case. (PX7140 (Rothman Trial Dep. at 9)). And though he does not have any pre-existing expertise related to the listed topics, he has relied on the factual record, other

experts, and the testimony of witnesses who do have such expertise, and he has analyzed this information as it relates to the efficiencies claimed by Respondents' experts. (PX7140 (Rothman Trial Dep. at 13-14)).

The proposed finding is vague. Respondents fail to define the terms [redacted] Therefore, this Court should disregard the proposed finding.

2194.7 Dr. Rothman lacks experience with medical device evidence generation and medical technology risk-sharing agreements. (PX7140 (Rothman Trial Dep. at 46.)

Response to Finding No. 2194.7

[redacted]

[redacted]

The proposed finding is further misleading to the extent it implies that Dr. Rothman must be an expert in any of the listed areas to formulate and express an appropriate opinion regarding the efficiencies claimed by Respondents' experts. Dr. Rothman does not hold himself out as having any particular expertise with respect to FDA approval, payer reimbursement, medical technology risk sharing agreements, medical device collaborations, [redacted] Rather, as he explained, Dr. Rothman is an expert in evaluating "competitive effects as well as efficiencies," of mergers including the efficiencies Respondents claim here, which he has learned about throughout the case. (PX7140 (Rothman Trial Dep. at 9)). And though he does not have any pre-existing expertise related to the listed topics, he has relied on the factual record, other experts, and the testimony of witnesses who do have such expertise, and he has analyzed this information as it relates to the efficiencies claimed by Respondents' experts. (PX7140 (Rothman Trial Dep. at 13-14)).

The proposed finding is vague. Respondents fail to define the terms "lacks experience," "medical device evidence generation," and "medical technology risk-sharing agreements." Therefore, this Court should disregard the proposed finding.

2195. [redacted]

Response to Finding No. 2195

[redacted]

[redacted]

[redacted]

[redacted]

2196. [redacted]

Response to Finding No. 2196

[redacted]

[redacted]

[redacted]

2197. [redacted]

Response to Finding No. 2197

[redacted]

[redacted]

2198. [redacted]

Response to Finding No. 2198

[redacted]

[redacted]

2199. [redacted]

Response to Finding No. 2199

[redacted]

[redacted]

2199.1 [redacted]

Response to Finding No. 2199.1

[redacted]

[redacted]

2199.2 [redacted]

Response to Finding No. 2199.2

[redacted]

[redacted]

[redacted]

2199.3 [redacted]

Response to Finding No. 2199.3

[redacted]

[redacted]

2199.4 [redacted]

Response to Finding No. 2199.4

[redacted]

[redacted]

[redacted]

2199.5 [redacted]

Response to Finding No. 2199.5

[redacted]

[redacted]

2199.6 [redacted]

Response to Finding No. 2199.6

[redacted]

2199.7 [redacted]

Response to Finding No. 2199.7

[redacted]

[redacted]

2200. [redacted]

Response to Finding No. 2200

[redacted]

2201. [redacted]

Response to Finding No. 2201

[redacted]

2201.1 [redacted]

Response to Finding No. 2201.1

[redacted]

2201.2 [redacted]

Response to Finding No. 2201.2

[redacted]

2201.3 [redacted]

Response to Finding No. 2201.3

[redacted]

[redacted]

2202. [redacted]

Response to Finding No. 2202

[redacted]

2203. {[redacted]

Response to Finding No. 2203

[redacted]

[redacted]

2204. [redacted]

Response to Finding No. 2204

[redacted]

[redacted]

2205. [redacted]

Response to Finding No. 2205

[redacted]

[redacted]

2206. [redacted]

Response to Finding No. 2206

[redacted]

COMPLAINT COUNSEL'S RESPONSES

TO RESPONDENTS' PROPOSED CONCLUSIONS OF LAW

I. LEGAL STANDARD AND BURDEN OF PROOF

1. Complaint Counsel seeks an injunction unwinding the reunion of Illumina and GRAIL under Section 7 of the Clayton Act. (Compl. at 28.)

Response to Proposed Conclusion No. 1

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by this Court's March 23, 2021 Order on Post-Trial Filings, at 2. Consequently, the Proposed Conclusion should be disregarded.

The contents of the Proposed Conclusion are misleading and incomplete. Complaint Counsel sought an injunction preventing Illumina from acquiring Grail under Section 7 of the Clayton Act on March 30, 2021. *In re Illumina, Inc. and Grail, Inc.*, Complaint, Docket No. 9401, at 28 (F.T.C. Mar. 30, 2021) [hereinafter "Complaint"]. The Complaint was issued prior to Illumina's decision to consummate the Acquisition, which it consummated during this litigation on August 18, 2021. *See* (CCFF ¶ 200). Thus, by Illumina's own actions, it now must unwind the transaction if this Court grants an injunction.

The Proposed Conclusion is misleading to the extent it suggests that the fact that Illumina once owned a majority interest in Grail somehow inoculates the illegal transaction. Not only does this have no basis in law, *see Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768-69 (1984) (explaining, in a non-merger antitrust case, that when "two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit" it "deprives the marketplace of the independent centers of decision making that competition assumes and demands"), but this is not the virtuous reunion that Respondents claim.

Rather, Illumina discarded Grail as soon as it became "untenable" for Illumina to continue to invest. (CCFF ¶ 44). Illumina knew that once it rid itself of majority ownership, Grail could either sink or swim—and if Grail succeeded, it would be an entirely different company than the fledgling start-up Illumina formed. Without help from Illumina, Grail and Illumina pursued their own interests, moving from a collaborative partnership to an arms-length supplier-customer relationship. [redacted] Only now that Illumina no longer needs to invest the immense time and resources in the research and development of MCED tests does Illumina want Grail back. Rather than immunize the potential harm from the Acquisition, the reunion story merely highlights the futility of Illumina's involvement in Grail's success and, accordingly, the baselessness of Respondents' procompetitive efficiency claims. For the reasons stated above, the Proposed Conclusion should be disregarded.

2. Complaint Counsel bears "the burden on every element of their Section 7 challenge." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116 (D.D.C. 2004).

Response to Proposed Conclusion No. 2

The Proposed Conclusion is vague to the extent it does not define "burden"—e.g., whether it is a burden of persuasion, burden of production, or something else—and does not define the "element[s]" for which Complaint Counsel bears the undefined "burden."

The Proposed Conclusion is incomplete and thus misleading. While Complaint Counsel bears the ultimate burden of persuasion on its Section 7 claim, Respondents bear the burden of proof for their factual claims and defenses.

Courts and the Commission have traditionally analyzed Section 7 claims under a burden-shifting framework outlined in *Baker Hughes* and its progeny, *see United States v. Baker*

Hughes, Inc., 908 F.2d 981, 982-83 (D.C. Cir. 1990); *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *11 (F.T.C. Nov. 1, 2019); *In re Polypore Int'l, Inc.*, Docket No. D-9327, 2010 WL 9549988, at *9 (F.T.C. Nov. 5, 2010), and the same burden-shifting framework applies to both horizontal and vertical mergers. *See United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 191 n.17 (D.D.C. 2018) (rejecting, "as a matter of law and logic," defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the Government "has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case"). Respondents do not dispute that the *Baker Hughes* burden-shifting framework applies here. Resp. Pre-Trial Br. at 43.

Under this burden-shifting framework, "[f]irst, the government must establish a prima facie case that an acquisition is unlawful." *Polypore*, 2010 WL 9549988, at *9; *see also Baker Hughes*, 908 F.2d at 982. "The burden of producing evidence to rebut [the *prima facie* case] then shifts to the defendant." *Baker Hughes*, 908 F.2d at 982. "If the defendant successfully rebuts the [*prima facie* case], the burden of producing additional evidence of anticompetitive effect shifts to the government, and mergers with the ultimate burden of persuasion, which remains with the government at all times." *Id.* at 983. Although Complaint Counsel has the ultimate burden in this case, Respondents bear the burden of proving their factual propositions. Initial Decision, *In re Altria Group, Inc. and Juul Labs, Inc.*, Docket No. 9393, at 5 (F.T.C. Feb. 15, 2022) ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)). For the reasons stated above, the Proposed Conclusion should be disregarded.

3. Complaint Counsel's "failure of proof in any respect will mean the transaction should not be enjoined." *Arch Coal*, 329 F. Supp. 2d at 116.

Response to Proposed Conclusion No. 3

The Proposed Conclusion is vague because it does not define "failure of proof," the burden related to such "proof," or what constitutes "failure" of proof.

The Proposed Conclusion is incomplete and thus misleading. While Complaint Counsel bears the ultimate burden of persuasion on its Section 7 claim, Respondents bear the burden of proof for their factual claims and defenses.

Courts and the Commission have traditionally analyzed Section 7 claims under a burden-shifting framework outlined in *Baker Hughes* and its progeny, *see United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990); *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *11 (F.T.C. Nov. 1, 2019); *In re Polypore Int'l, Inc.*, Docket No. D-9327, 2010 WL 9549988, at *9 (F.T.C. Nov. 5, 2010), and the same burden-shifting framework applies to both horizontal and vertical mergers. *See United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 191 n.17 (D.D.C. 2018) (rejecting, "as a matter of law and logic," defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the Government "has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case"). Respondents do not dispute that the *Baker Hughes* burden-shifting framework applies here. Resp. Pre-Trial Br. at 43.

Under this burden-shifting framework, "[f]irst, the government must establish a prima facie case that an acquisition is unlawful." *Polypore*, 2010 WL 9549988, at *9; *see also Baker Hughes*, 908 F.2d at 982. "The burden of producing evidence to rebut [the *prima facie* case] then shifts to the defendant." *Baker Hughes*, 908 F.2d at 982. "If the defendant successfully rebuts the [*prima facie* case], the burden of producing additional evidence of anticompetitive effect shifts to the government, and mergers with the ultimate burden of persuasion, which

remains with the government at all times." *Id.* at 983. Although Complaint Counsel has the ultimate burden in this case, Respondents bear the burden of proving their factual propositions. Initial Decision, *In re Altria Group, Inc. and Juul Labs, Inc.*, Docket No. 9393, at 5 (F.T.C. Feb. 15, 2022) ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)). For the reasons stated above, the Proposed Conclusion should be disregarded.

4. To prove a violation of the Clayton Act, Complaint Counsel must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Illumina and GRAIL, "at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts." *U.S. v. AT&T* (*AT&T I*), 310 F. Supp. 3d 161, 194 (D.D.C. 2018).

Response to Proposed Conclusion No. 4

The Proposed Conclusion mischaracterizes the *AT&T* district court opinion, which in context states that the procompetitive benefits were conceded and therefore not implicated by any burden shifting. The full quote states, "The case at hand therefore turns on whether, notwithstanding the proposed merger's *conceded* procompetitive effects, the Government has met its burden of proof of establishing, through case-specific evidence, that the merger of AT&T and Time Warner, at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts." *United States v. AT&T*, 310 F. Supp. 3d 161, 194 (D.D.C. 2018) (citations and quotations omitted) (emphasis added).

The Proposed Conclusion is misleading and incomplete. Courts and the Commission have traditionally analyzed Section 7 claims under a burden-shifting framework outlined in *Baker Hughes* and its progeny, *see United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990); *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *11 (F.T.C. Nov. 1, 2019); *In re Polypore Int'l, Inc.*, Docket No. D-9327, 2010 WL 9549988, at *9 (F.T.C.

Nov. 5, 2010), and the same burden-shifting framework applies to both horizontal and vertical mergers. *See United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 191 n.17 (D.D.C. 2018) (rejecting, "as a matter of law and logic," defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the Government "has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case"). Respondents do not dispute that the *Baker Hughes* burden-shifting framework applies here. Resp. Pre-Trial Br. at 43.

Under this burden-shifting framework, "[f]irst, the government must establish a prima facie case that an acquisition is unlawful." *Polypore*, 2010 WL 9549988, at *9; *see also Baker Hughes*, 908 F.2d at 982. "The burden of producing evidence to rebut [the *prima facie* case] then shifts to the defendant." *Baker Hughes*, 908 F.2d at 982. "If the defendant successfully rebuts the [*prima facie* case], the burden of producing additional evidence of anticompetitive effect shifts to the government, and mergers with the ultimate burden of persuasion, which remains with the government at all times." *Id.* at 983. Although Complaint Counsel has the ultimate burden in this case, Respondents bear the burden of proving their factual propositions. Initial Decision, *In re Altria Group, Inc. and Juul Labs, Inc.*, Docket No. 9393, at 5 (F.T.C. Feb. 15, 2022) ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)). For the reasons stated above, the Proposed Conclusion should be disregarded.

5. Although Section 7 requires "making a prediction about the future", and deals with probabilities, *id.* at 189–91, it does not permit blocking a merger based on speculative "possibilities", *id.*, or "guesswork", and it does not permit ignoring the actual facts. *FTC v. AG-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020) ("[A]ntitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence

relating to the market and its probable future." (quoting *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004))).

Response to Proposed Conclusion No. 5

The Proposed Conclusion is misleading and incomplete. Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or in any activity affecting commerce in any section of the country[.]" 15 U.S.C. § 18. "Congress used the words '*may be* substantially to lessen competition' [] to indicate that its concern was with probabilities, not certainties[.]" *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 337 (3d Cir. 2016) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962) (emphasis in original); *see also In re Tronox Ltd.*, Docket No. 9377, 2018 WL 6630200, at *6 (F.T.C. Dec. 14, 2018) ("[I]t is not necessary to demonstrate certainty that a proposed merger will produce anticompetitive effects, or even that such effects are highly probable, but only that the loss of competition is a sufficiently probable and imminent result of the merger or acquisition.") (quotations and citations omitted). Consequently, the Proposed Conclusion should be disregarded.

As described in its post-trial briefing, Complaint Counsel has adduced overwhelming evidence that the Acquisition poses a reasonable probability of harming ongoing competition. Respondents, in contrast, have utterly failed to put forth any "actual facts" that would suggest otherwise, meanwhile engaging in mere "guesswork" in their attempts to rebut Complaint Counsel's robust evidence. *See generally* Complaint Counsel's Post-Trial Brief; Complaint Counsel's Post-Trial Reply Brief For the reasons stated above, the Proposed Conclusion should be disregarded.

6. Complaint Counsel must therefore prove that "the challenged acquisition [is] *likely* substantially to lessen competition." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115 (D.D.C. 2004) (emphasis added); *see United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974) (alleged future harm to competition must be "sufficiently probable and imminent" to

warrant relief); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1109 (N.D. Cal. 2004) (rejecting merger challenge because government failed to prove the "merger will *likely* lead to a substantial lessening of competition") (emphasis added); *In re Altria Grp., Inc.*, FTC No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted."); *see also FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1051 (8th Cir. 1999) ("Section 7 deals in probabilities not ephemeral possibilities.").

Response to Proposed Conclusion No. 6

The Proposed Conclusion is misleading and incomplete. First, it overstates Complaint Counsel's burden. Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or in any activity affecting commerce in any section of the country[.]" 15 U.S.C. § 18. "Congress used the words '*may be* substantially to lessen competition' [] to indicate that its concern was with probabilities, not certainties[.]" *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 337 (3d Cir. 2016) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962) (emphasis in original); *see also In re Tronox Ltd.*, Docket No. 9377, 2018 WL 6630200, at *6 (F.T.C. Dec. 14, 2018) ("[I]t is not necessary to demonstrate certainty that a proposed merger will produce anticompetitive effects, or even that such effects are highly probable, but only that the loss of competition is a sufficiently probable and imminent result of the merger or acquisition.") (quotations and citations omitted). As the Supreme Court described in *Brown Shoe*, "it is necessary to examine the effects of a merger in each [relevant market] to determine if there is a *reasonable probability* that the merger will substantially lessen competition." *Brown Shoe*, 370 U.S. at 325 (emphasis added). As Complaint Counsel has shown in its post-trial briefing, Complaint Counsel has met its burden to show that the Acquisition has a reasonable probability to substantially lessen competition. [redacted]

Second, the Proposed Conclusion misstates the legal standard for assessing future

competitive conditions. When analyzing the competitive harm under the Clayton Act, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" *Aetna,* 240 F. Supp. 3d at 79 (internal citation omitted). As this Court explained in *In re Altria Group, Inc. and Juul Labs, Inc.*, this means looking at whether competition "would have existed in the 'near future,'" where "near" is "defined in terms of the entry barriers and lead time necessary for entry in the particular industry." Initial Decision, *Altria*, Docket No. 9393, at 106, 111-12 (quoting *BOC Int'l, Ltd. v. FTC*, 557 F.2d 24, 29 (2d Cir. 1977). Accordingly, the Proposed Conclusion's cited language about the ability to predict competitive conditions in a completely different market is irrelevant, [redacted] Consequently, the Proposed Conclusion should be disregarded.

7. Because the Transaction is purely vertical, Complaint Counsel "cannot use a short cut to establish a presumption of anticompetitive effect"; rather, it must make a "fact-specific" showing that the Transaction is anticompetitive. *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve.").

Response to Proposed Conclusion No. 7

While Complaint Counsel has no specific response regarding a competitive effects inquiry being "fact-specific," the Proposed Conclusion is misleading and incomplete. As one of Respondents' heavily cited cases states, there is a *per se* rule that potential foreclosure "amount[s] to a violation of § 7" when "the share of the market foreclosed reaches monopoly proportions." *Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir.1979) (citations omitted); *see also Brown Shoe,* 370 U.S. at 328-29 (noting that "the Clayton Act will, of course, have been violated" where "the share of the market foreclosed is so large that it approaches monopoly

proportions").

The Proposed Conclusion's reliance on *Republic Tobacco* is misplaced. The quote from *Republic Tobacco* describes different standards for analyzing conspiracies under the Sherman Act, explaining that agreements between competitors are "generally more suspect" than supplier-customer agreements. *Republic Tobacco Co. v. North Alt. Trading Co.*, 381 F.3d 717, 736-37 (7th Cir. 2004). That case does not provide any legal standards under Section 7 of the Clayton Act, and the "legislative history of § 7 indicates clearly that the tests for measuring the legality of any particular economic arrangement under the Clayton Act are to be less stringent than those used in applying the Sherman Act." *Brown Shoe*, 370 U.S. at 328-29. Consequently, the Proposed Conclusion should be disregarded.

8. Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the Transaction.

Response to Proposed Conclusion No. 8

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by this Court's March 23, 2021 Order on Post-Trial Filings, at 2. Consequently, the Proposed Conclusion should be disregarded.

The Proposed Conclusion also overstates Complaint Counsel's burden. Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or in any activity affecting commerce in any section of the country[.]" 15 U.S.C. § 18. "Congress used the words '*may be* substantially to lessen competition' [] to indicate that its concern was with probabilities, not certainties[.]" *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 337 (3d Cir. 2016) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962) (emphasis in original); *see also In re Tronox Ltd.*,

Docket No. 9377, 2018 WL 6630200, at *6 (F.T.C. Dec. 14, 2018) ("[I]t is not necessary to demonstrate certainty that a proposed merger will produce anticompetitive effects, or even that such effects are highly probable, but only that the loss of competition is a sufficiently probable and imminent result of the merger or acquisition.") (quotations and citations omitted). As Complaint Counsel has shown in its post-trial briefing, Complaint Counsel has met its burden to show that the Acquisition has a reasonable probability to substantially lessen competition. [redacted]

For the reasons stated above, the Proposed Conclusion should be disregarded.

9. Complaint Counsel cannot sustain its burden merely by showing that the Transaction may disadvantage some of GRAIL's putative rivals vis-à-vis GRAIL—for example, as a result of GRAIL becoming a more efficient competitor through vertical integration—because "[t]he antitrust laws . . . were enacted for the protection of competition not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977). Rather, Complaint Counsel must demonstrate that GRAIL rivals would be foreclosed "in a substantial share" of a well-defined relevant product market, enabling Illumina to suppress innovation and output, and raise prices. *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 595 (1957); *see also Fruehauf Corp. v. FTC,* 603 F.2d 345, 352 n.9 (2d Cir. 1979); *McWane Inc. v. FTC*, 783 F.3d 814, 838–39 (11th Cir. 2015).

Response to Proposed Conclusion No. 9

The Proposed Conclusion is vague because it does not define "well-defined" or "substantial share." It also is vague as to whether it is suggesting Complaint Counsel must show that Illumina would be able to suppress innovation and output and raise prices, or whether the Proposed Conclusion is suggesting any one of those harms would be sufficient on its own.

The Proposed Conclusion's hypothetical scenario in which Grail becomes a more is irrelevant because it is not the case here. Moreover, the Proposed Conclusion is misleading and incomplete. Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or in any activity affecting commerce in any section of the country[.]" 15 U.S.C. § 18. Indeed, as

the Supreme Court explained, "Taken as a whole, the legislative history [behind amending the Clayton Act to reach vertical mergers] illuminates congressional concern with the protection of competition, not competitors, and its desire to restrain mergers only to the extent that such combinations may tend to lessen competition." *Brown Shoe*, 370 U.S. at 320. And according to the Supreme Court, the "primary vice of a vertical merger . . . is that, by foreclosing the competitors of either party from a segment of the market otherwise open to them, the arrangement may act as a clog on competition, which deprives rivals of a fair opportunity to compete." *Id.* at 323-24 (internal citations and quotations omitted). Thus, Congress sought to protect *competition*—not competitors—by preventing vertical mergers that "may act as a clog on competition," and ultimately ensuring "rivals [have] a fair opportunity to compete." *Id.* at 324 (internal quotations omitted). Consequently, the Proposed Conclusion should be disregarded.

II. COMPLAINT COUNSEL FAILED TO PROVE THE REQUISITE ANTITRUST MARKETS

A. Complaint Counsel Failed To Prove Its Alleged Relevant Market

10. Defining the relevant market is a "necessary predicate" to finding a Clayton Act violation because the statute proscribes only mergers that "will substantially lessen competition within the area of effective competition." *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (internal quotations omitted); *see United States v. Baker Hughes Inc.*, 908 F.2d 981, 982 (D.C. Cir. 1990) (government must show "that a transaction will lead to undue concentration in the market for a particular product"). Defining a relevant market is necessary because the scope of the relevant market dictates the analysis of market power and a merger's potential anticompetitive effects. *See United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 181 (D.D.C. 2001).

Response to Proposed Conclusion No. 10

The Proposed Conclusion is a misleading and contrary to the law. While Complaint Counsel agrees that "[d]etermination of the relevant market is a necessary predicate to a finding of a violation of the Clayton Act," *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957), the proposed conclusion mischaracterizes the purpose of market definition.

Market definition is not an end to itself. As the Clayton Act makes clear, the purpose of market definition is to illuminate the competitive effects of the merger. 15 U.S.C. § 18 (requiring identification of a "line of commerce" effected by the anticompetitive merger); U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines (2010) § 4 [hereinafter *Horizontal Merger Guidelines*] ("The measurement of market shares and market concentration is not an end in itself, but is useful to the extent it illuminates the merger's likely competitive effects."). Here, Complaint Counsel alleges that the Acquisition will harm competition [redacted] In support of its allegations, Complaint Counsel defined a relevant market—[redacted] As shown in its post-trial brief, Complaint Counsel's market definition is firmly supported by caselaw, established antitrust principles, and a voluminous trial record. *Id.* Nothing in Respondents' post-trial brief undermines this conclusion. For the reasons stated above, the Proposed Conclusion should be disregarded.

11. Complaint Counsel "bears the burden of proof and persuasion in defining the relevant market." *Arch Coal*, 329 F. Supp. 2d at 118. If it is unable to carry that burden, then the its case fails. *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 291 (D.D.C. 2020) ("Defining the relevant market is a necessary predicate to finding a Clayton Act violation because the proposed merger must be one which will substantially lessen competition within the area of effective competition.") (citations and quotations omitted); *see also Determined Prods. v. R. Dakin Co.*, 514 F. Supp. 645, 648 (N.D. Cal. 1979), *aff'd*, 649 F.2d 866 (9th Cir. 1981) ("Plaintiff must [] come forward with evidence of the relevant market. Failure to do so entitles defendant to judgment.").

Response to Proposed Conclusion No. 11

The Proposed Conclusion is misleading and incomplete. Section 7 of the Clayton Act prohibits acquisitions "where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen

competition, or to tend to create a monopoly." 15 U.S.C. § 18. The Supreme Court has recognized that Section 7 thereby prohibits acquisitions that would "substantially lessen competition within the area of effective competition." *Brown Shoe*, 370 U.S. at 324 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957) (internal quotations omitted). To determine the "area of effective competition," courts "reference . . . a product market (the 'line of commerce') and a geographic market (the 'section of the country')[.]" *Brown Shoe*, 370 U.S. at 324. "Often, the first steps in analyzing a merger's competitive effects are to define the geographic and product markets affected by it." *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 565 (6th Cir. 2014). Whether the transaction at issue is horizontal or vertical, courts use the same set of analytic tools to define the affected market. *See Brown Shoe*, 370 U.S. at 324-28.

It is well settled that "the boundaries of the relevant market must be drawn with sufficient breadth to . . . recognize competition where, in fact, competition exists." *Brown Shoe*, 370 U.S. at 326. A product market's "outer boundaries" are determined by the "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 198 (D.D.C. 2018) (quoting *Brown Shoe*, 370 U.S. at 325). To make this determination, courts generally look to two types of evidence: "the 'practical indicia' set forth by the Supreme Court in *Brown Shoe*, and testimony from experts in the field of economics." *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 27 (D.D.C. 2015). Here, both practical indicia and economic testimony are sufficient to define the relevant product market as the MCED Test Market. For the reasons stated above, the Proposed Conclusion should be disregarded.

12. Here, Complaint Counsel's alleged market fails for five, independent reasons: (1) it is impermissibly speculative and simultaneously over- and under-inclusive; (2) it disregards

"reasonable interchangeability and cross-elasticity of demand"; (3) it runs counter to the Supreme Court's *Brown Shoe* factors; (4) it flunks the Hypothetical Monopolist Test; and (5) it depends on the agency's subjective and changing policy assessments, rather than established law and objective evidence.

Response to Proposed Conclusion No. 12

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is also contrary to the weight of the evidence. [redacted] For the reasons stated above, the Proposed Conclusion should be disregarded.

1. **The Alleged Relevant Market Is Impermissibly Speculative and Simultaneously Over- and Under-Inclusive**

13. To meet its burden, Complaint Counsel was required to adduce admissible evidence proving its alleged relevant market, not mere speculation. *See Reifert v. S. Cent. Wisconsin MLS Corp.*, 450 F.3d 312, 318 (7th Cir. 2006) ("a conclusory assumption of competition where products or services appear to be similar is insufficient" to prove a relevant product market); *Arch Coal*, 329 F. Supp. 2d at 117 (D.D.C. 2004) ("[A]ntitrust theory and speculation cannot trump facts"). It was also required to draw a market that was neither over- nor under-inclusive. *See Arch Coal*, 329 F. Supp. 2d at 120 (holding that the relevant product market was "no broader and no narrower than the SPRB coal" based on the "narrowest market" principle); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 58–60 (D.D.C. 2011) ("[T]he relevant product market should ordinarily be defined as the smallest product market that will satisfy the hypothetical monopolist test"). Complaint Counsel fell far short: (a) its proposed market is impermissibly speculative because other than Galleri, it consists entirely of products that are still in development, some in very early stages, and (b) its proposed market is simultaneously over- and under-inclusive, as it includes putative MCED tests that, if and when launched, will not be viewed by physicians or patients as substitutes for Galleri, and it excludes screening tests that use non-NGS technology.

Response to Proposed Conclusion No. 13

The Proposed Conclusion misleading, incomplete, contrary to the law, and against the weight of the evidence. Moreover, to the extent that Respondents are making the factual contention that Complaint Counsel's proposed market is speculative, the Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded. Moreover, Respondents' Proposed Conclusion is also contrary to the weight of the evidence. As Respondents recognize and *Arch Coal*, , explains "antitrust theory and speculation cannot trump facts." 329 F. Supp. 2d at 117. Here Complaint Counsel has adduced facts in support of its market definition. [redacted]

Respondents' Proposed Conclusion is misleading and contrary to the law as it misunderstands the "key question" on market definition. Complaint Counsel alleges that the merger poses a reasonable probability of substantially lessening competition in the market for research, development, and commercialization of MCED tests. Thus, the key question on market definition is whether that is a valid relevant market. Whether and to what extent Grail participates in that market is probative regarding the proposed merger's likely effects. To the extent Respondents argue that Complaint Counsel needs to conduct a brand-by-brand inquiry they misunderstand the purpose of the *Brown Shoe* test. The *Brown Shoe* test is not designed to

invariably identify the narrowest possible product market. *Brown Shoe*, 370 U.S. at 325 (recognizing that a broader market or a narrower "submarket" could both be valid relevant markets in a given case). Nor is the hypothetical monopolist test designed to identify only the narrowest possible market in a given case. As the Horizontal Merger Guidelines recognize, "[t]he hypothetical monopolist test ensures that markets are not defined too narrowly, but it does not lead to a single relevant market. The Agencies may evaluate a merger in any relevant market satisfying the test, guided by the overarching principle that the purpose of defining the market and measuring market shares is to illuminate the evaluation of competitive effects." *Horizontal Merger Guidelines* § 4.1.1. Here, defining a narrower market that excludes Galleri would exclude competition among MCED test developers and Galleri indicating that a sans-Galleri MCED market is too narrow to illuminate the evaluation of competitive effects.

Finally, the Proposed Conclusion is contrary to the weight of the evidence that shows [redacted] For the reasons stated above, the Proposed Conclusion should be disregarded.

14. While courts have interpreted the language in Section 7 to infer that Congress's "concern was with probabilities, not certainties", that language was "intended to allow courts to appreciate immediately the potential consequences that a particular acquisition might have upon an *existing line of commerce*." *SCM Corp. v Xerox Corp.*, 645 F.2d 1195, 1211 (2d. Cir. 1981) (emphasis added) (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962)). Thus, it is "[t]he existing market [which] provides the framework in which the probability and extent of an adverse impact upon competition may be measured." *SCM Corp.*, 645 F.2d at 1211. Complaint

Counsel may not—as it does here—rely exclusively on speculation about future markets to support its alleged antitrust market. *Arch Coal*, 329 F. Supp. 2d at 116–17.

Response to Proposed Conclusion No. 14

To the extent that Respondents are making the factual contention that Complaint Counsel's proposed market is does not exist, the Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Moreover, Respondents' assertion is contrary the weight of the evidence. As Respondents acknowledge, [redacted] As Kevin Conroy, CEO of Exact, explained, "I believe there is a nascent market that has begun once Galleri became available." (Conroy (Exact) Tr. 1738)

While Respondents have accurately quoted *SCM Corp.*, the Proposed Conclusion is misleading to the extent it suggests that Complaint Counsel can only define a fully-developed market. Rather the court in *SCM Corp. v. Xerox Corp.* explained that "[t]he existing market provides the framework in which the probability and extent of an adverse impact upon competition may be measured." 645 F.2d 1195, 1211 (2d. Cir. 1981). In that case, the acquisition could not impact competition because the acquired patents barred said competition. *Id.* ("Where, as here, it is conceded that the relevant product market and submarket did not exist until eight years following the patent acquisitions and that Xerox possessed no power whatsoever in even the inchoate market and submarket until 1960 when it introduced its 914 copier, as a matter of law the 1956 agreement did not violate § 7 at the time it was made."). [redacted]

[redacted] For the reasons stated above, the Proposed Conclusion should be disregarded.

15. The fact that the hypothesized MCED market proposed by Complaint Counsel does not, in fact, exist is significant because courts have held that where a market does not exist, there can be no anticompetitive effects. *Kenney v. Am. Bd. of Internal Med.*, 412 F. Supp. 3d 530, 547 (E.D. Pa. 2019), *aff'd*, 847 F. App'x 137 (3d Cir. 2021) (holding that Defendant "cannot have a monopoly in a market that does not exist."); *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 480 (7th Cir. 1988) ("It is impossible to monopolize a market that does not exist."); *Siva v. Am. Bd. of Radiology*, 418 F. Supp. 3d 264, 277 (N.D. Ill. 2019) (holding that a defendant cannot have or exploit a "monopoly in a market that does not exist."); *In re Altria Grp., Inc.*, No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted.").

Response to Proposed Conclusion No. 15

To the extent that Respondents are making the factual contention that Complaint Counsel's proposed market is does not exist, the Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

Respondents' Proposed Conclusions are misleading and contrary to the law. All but one case cited by Respondents are Section 2 Sherman Act cases. Congress intended Section 7 to have a lower standard than the Sherman Act for judging the legality of business combinations, and as such these cases are inapposite. *Brown Shoe*, 370 U.S. at 318 ("Congress rejected, as inappropriate to the problem it sought to remedy, the application to § 7 cases of the standards for judging the legality of business combinations adopted by the courts in dealing with cases arising under the Sherman Act, and which may have been applied to some early cases arising under original § 7."). Moreover, the inquiry in each of these Section 2 cases is fundamentally different. As Respondents admit, Plaintiffs in those cases alleged monopolization of a particular market.

Kenney v. Am. Bd. of Internal Med., 412 F. Supp. 3d 530, 548 (E.D. Pa. 2019) (holding that Defendant "cannot have a monopoly in a market that does not exist"), *aff'd*, 847 F. App'x 137 (3d Cir. 2021); *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 480 (7th Cir. 1988) ("It is impossible to monopolize a market that does not exist."); *Siva v. Am. Bd. of Radiology*, 418 F. Supp. 3d 264, 277 (N.D. Ill. 2019) (holding that a defendant cannot have or exploit a "monopoly in a market that does not exist."). Here, Complaint Counsel has alleged a fundamentally different type of harm: namely, that "[t]he Acquisition would substantially lessen competition in the market for the research, development, and commercialization of MCED tests in the United States." Complaint, *Illumina*, Docket No. 9401, ¶ 31 ; *see generally* [redacted] The one case Respondents cite that involves a Section 7 claim—*In re Altria Grp., Inc.*, No. 939—defined a market prior to the market being fully mature. Initial Decision, *Altria*, No. 9393, at 22.). For the reasons stated above, the Proposed Conclusion should be disregarded.

16. Courts have repeatedly rejected alleged markets defined to include products that are not yet in existence and whose features are highly uncertain, and have rejected the inclusion of undefined future products in a relevant market. *See SCM Corp.*, 645 F.2d at 1211 (overturning jury verdict in plaintiffs' favor and holding that patent acquisitions did not violate Section 7 as a matter of law because the relevant product market did not exist at the time of the acquisitions and for another eight years following the acquisitions); *Fraser v. Major League Soccer, L.L.C.*, 97 F. Supp. 2d 130, 140 (D. Mass. 2000), *aff'd*, 284 F.3d 47 (1st Cir. 2002) ("The relevant test under § 7 looks to whether competition in *existing* markets has been reduced. Where there is no existing market, there can be no reduction in the level of competition. . . . Competition that does not exist cannot be decreased."); *Epic Games, Inc. v. Apple Inc.*, 2021 WL 4128925 at *56 (N.D. Cal. 2021) (excluding the offerings of certain gaming companies from the relevant product submarket because the record was limited as to those companies, and they were "too new for a determination of whether they should or should not be included in the relevant product market"); *Apartment Source of Pa., L.P. v. Phila. Newspapers, Inc.*, No. CIV. A. 98–5472, 1999 WL 349938, at *22–24 (E.D. Pa. May 21, 1999) (finding in defendants' favor because plaintiffs' alleged market was at most an "emerging market" within an apparent broader market and was not a well-defined separate market); *Crucible, Inc. v. Stora Kopparbergs Bergslags AB*, 701 F. Supp 1157, 1161 (W.D. Pa. 1988) ("Regarding the 1966 acquisition of the Battelle patents, a finding of no relevant market in PM high speed steel products is mandated by the fact that commercial production and marketing of

PM high speed steel products in the United States did not begin until 1971, four years after the patent acquisitions".).

Response to Proposed Conclusion No. 16

This is not a proposed conclusion of law to the extent that it makes factual conclusions contending that the products in Complaint Counsel's alleged market are "not yet in existence" or have "highly uncertain" features. Moreover, it is unsupported by any record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is also misleading and contrary to the law. In the first instance *SCM Corp.*, 645 F.2d at 1211 is in apposite for the reasons explained in Complain Counsel's Response to Proposed Conclusion No. 14. Case law instead makes clear that competition can be protected and markets defined where entry is ongoing or the market is not yet fully mature. *See, e.g., FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013) (recognizing that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" despite their being only the monopolist patent holder on the "market" to date); *Altitude Sports & Entertainment, LLC v. Comcast Corp.*, 2020 WL 8255520, at *13-14 (D. Colo. Nov. 25, 2020) (holding that plaintiffs' allegations of harm to a market that defendants had yet to participate in were sufficiently pleaded); *Ford Motor Co. v. United States*, 405 U.S. 562, 571 (1972) (analyzing the effect of a vertical merger on downstream barriers to entry). Courts have also made clear that participants in the market need not have a product for sale to be properly included in a relevant product market. *United States v. Bazaarvoice, Inc.*, 2014 WL 203966, at *70 (N.D. Cal. Jan. 8, 2014) (agreeing that firms who are entering the market may be considered "market participants and may be assigned market shares" for the purposes of antitrust analysis) (quoting *Horizontal Merger Guidelines* § 9); *Town Sound & Custom Tops, Inc. v. Chrysler*

Motors Corp., 959 F.2d 468, 480 (3d Cir. 1992) (holding that courts have also routinely defined an antitrust market that "includes actual or potential competitors who may take business away from each other") (citing *SmithKline Corp. v. Eli Lilly & Co.,* 575 F.2d 1056, 1063 (3d Cir. 1978)).

As Respondents' own cited cases explain, to identify competitive harm in a developing market, the relevant inquiry is not whether all putative products are for sale, but rather whether there is sufficient evidence to identify the competition at risk as a result of the alleged anticompetitive conduct. *See, e.g.*, *Fraser v. Major League Soccer, L.L.C.*, 97 F. Supp. 2d 130, 140 (D. Mass. 2000) (holding the creation of Major League Soccer did not violate Section 7 of the Clayton Act because there was no ongoing competition to protect and no acquisition or merger of an existing business enterprise); *Epic Games, Inc. v. Apple Inc.*, 559 F. Supp. 3d 898, 986-87 (N.D. Cal. 2021) ("[T]he Court must determine where the *actual* competition lies between these platforms . . . .") (emphasis in original); *Crucible, Inc. v. Stora Kopparbergs Bergslags AB*, 701 F. Supp. 1157, 1163 (W.D.PA 1988) ("Moreover, the court finds compelling the undisputed fact that the entities from which the patents were acquired (Battelle and IITRI) were not market competitors; nor were they even capable of commercially developing the patents."). For the reasons stated above, the Proposed Conclusion should be disregarded.

17. Where plaintiffs have tried to define a market based on speculative future products, courts have instead opted to define the market based on existing products. *Apartment Source*, 1999 WL 349938, at *1.

Response to Proposed Conclusion No. 17

The Proposed Conclusion is misleading and contrary to case law. *Apartment Source* is not illustrative. In the first instance, *Apartment Source* is a case brought under Section 2 of the Sherman Act. 1999 WL 349938 at *1. Congress intended Section 7 to have a lower standard than the Sherman Act for judging the legality of business combinations, and as such this case is

inapposite. *Brown Shoe*, 370 U.S. at 318 ("Congress rejected, as inappropriate to the problem it sought to remedy, the application to § 7 cases of the standards for judging the legality of business combinations adopted by the courts in dealing with cases arising under the Sherman Act, and which may have been applied to some early cases arising under original § 7."). Further, the *Apartment Source* court did not hold that a relevant product market could not be defined in a dynamic market, but rather only that the argued submarket was not a distinct market given that plaintiffs did not show "any evidence that apartment communities within the Philadelphia Region recognize apartment locator services as a separate economic reality." 1999 WL 349938 at *24. Unlike the submarket in that case, here there is ample evidence that [redacted] For these reasons, the Proposed Conclusion should be disregarded.

18. The fact that "courts have long applied antitrust laws to firms that have not yet entered or do not yet have sales in the relevant markets" (CC Pretrial Br. at 31) is no help to Complaint Counsel here. In those cases, courts blocked acquisitions between an incumbent firm and a potential competitor that demonstrated concrete plans to enter a mature, well-defined and—perhaps most critically—undisputed product market; none holds that products in early stage development should be considered part of the same relevant product market as a commercial product. For example, the court in *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208 (11th Cir. 2012) held that the acquired firm, Microporous, was an actual, rather than potential, competitor to Polypore in the SLI separator market based on its conduct and preparations to enter that market. 686 F.3d at 1214-15. There was no dispute as to the definition and contours of the SLI separator market. *Id*. Similarly, in *FTC v. Procter & Gamble Co.*, the Supreme Court held that a merger between Procter & Gamble and Clorox would eliminate potential competition of Procter & Gamble in the agreed-upon market for household liquid bleach. 386 U.S. 568, 571, 580 (1967). Complaint Counsel also cited *United States v. General Dynamics Corp.*, 415 U.S. 486, 501 (1974) for the proposition that "[e]vidence of past production does not, as a matter of logic, necessarily give a proper picture of a company's future ability to compete." (CC Pretrial Br. at 31.) The case plainly does not support Complaint Counsel's theory (and it is not apparent why Complaint Counsel believes it does): *General Dynamics* held that the vagaries of the coal production market are such that evidence of past market share is not as relevant a predictor of future strength as it would be in most markets. *Id.* Nothing in the decision supports including undefined products which are years from existence in a relevant product market.

Response to Proposed Conclusion No. 18

The Proposed Conclusion is both misleading and contrary to case law. In the first instance, [redacted] Moreover, the Proposed Conclusion is contradicted directly by well-established case law that explains that antitrust law is intended to protect competition in developing markets. *See, e.g., FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013) (recognizing that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" despite their being only the monopolist patent holder on the "market" to date); *Altitude Sports & Entertainment, LLC v. Comcast Corp.*, 2020 WL 8255520, at *13-14 (D. Colo. Nov. 25, 2020) (holding that plaintiffs' allegations of harm to a market that defendants had yet to participate in were sufficiently pleaded); *Ford Motor Co. v. United States*, 405 U.S. 562, 571 (1972) (analyzing the effect of a vertical merger on downstream barriers to entry). Courts have also made clear that participants in the market need not have a product for sale to be properly included in a relevant product market. *United States v. Bazaarvoice, Inc.*, 2014 WL 203966, at *70 (N.D. Cal. Jan. 8, 2014) (agreeing that firms who are entering the market may be considered "market participants and may be assigned market shares" for the purposes of antitrust analysis) (quoting *Horizontal Merger Guidelines* § 9); *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 480 (3d Cir. 1992) (holding that courts have also routinely defined an antitrust market that "includes actual or potential competitors who may take business away from each other") (citing *SmithKline Corp. v. Eli Lilly & Co.,* 575 F.2d 1056, 1063 (3d Cir. 1978)). For the reasons stated above, the Proposed Conclusion should be disregarded.

19. By defining the market to include tests that cannot be shown to be substitutes for Galleri or each other, Complaint Counsel's proposed market violates the narrowest market rule.

See FTC v. Arch Coal, Inc., 329 F. Supp. 2d 109, 120 (D.D.C. 2004) ("Relevant market analysis is based on the 'narrowest market' principle, the analysis of which requires "examining the most narrowly-defined product or group of products sold . . . [that] constitutes a relevant market"); (*see also* PPF ¶ 690.1 (Dr. Scott Morton "did not attempt to define the narrowest relevant market, you know, that would -- the narrowest market that would pass the hypothetical [monopolist] test, and I believe this is a fact, that she did not explain or offer a justification for why that would be appropriate. And that's not something that's relying on testimony by other people. It's a failure of the logic and the form of analysis that she's applied.").)

Response to Proposed Conclusion No. 19

The Proposed Conclusion misleading, incomplete, contrary to the law, and against the weight of the evidence. Moreover, to the extent that Respondents are making the factual contention that Complaint Counsel's Galleri is not a substitute for its MCED rivals, the Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is also misleading. As basic antitrust principles explain, the relevant question is not whether third-party market participants are close economic substitutes for each other but rather whether they are close substitutes for Galleri. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 914a (5th ed. 2021) (illustrating the competitive analysis in markets with heterogenous products, which assesses third parties' competition with the merged firm).

Respondents' Proposed Conclusion is misleading and contrary to the law as it misunderstands the "key question" on market definition. Complaint Counsel alleges that the Acquisition poses a reasonable probability of substantially lessening competition in the market for research, development, and commercialization of MCED tests. Thus, the key question on market definition is whether that is a valid relevant market. Whether and to what extent Grail participates in that market is probative regarding the proposed merger's likely effects. To the

extent Respondents argue that Complaint Counsel needs to conduct a brand-by-brand inquiry they misunderstand the purpose of the *Brown Shoe* test. The *Brown Shoe* test is not designed to invariably identify the narrowest possible product market. *Brown Shoe*, 370 U.S. at 325 (recognizing that a broader market or a narrower "submarket" could both be valid relevant markets in a given case). Nor is the hypothetical monopolist test designed to identify only the narrowest possible market in a given case. As the Horizontal Merger Guidelines recognize, "[t]he hypothetical monopolist test ensures that markets are not defined too narrowly, but it does not lead to a single relevant market. The Agencies may evaluate a merger in any relevant market satisfying the test, guided by the overarching principle that the purpose of defining the market and measuring market shares is to illuminate the evaluation of competitive effects." *Horizontal Merger Guidelines* § 4.1.1. Here, defining a narrower market that excludes Galleri would exclude competition among MCED test developers and Galleri indicating that a sans-Galleri MCED market is too narrow to illuminate the evaluation of competitive effects.

Finally, the Proposed Conclusion is contrary to the weight of the evidence that shows [redacted] Likewise, the Proposed Conclusion is contrary to the weight of the evidence that shows Complaint Counsel has not excluded substitutes from the market. [redacted] For the reasons stated above, the Proposed Conclusion should be disregarded.

20. Complaint Counsel's proposed market is also under-inclusive, because it excludes MCED tests that are not based on NGS technology. (PFF ¶ 690.) Complaint Counsel offers no basis for excluding these tests, which are currently on the market, from its proposed relevant market. *See Sungard Data Sys*, 172 F. Supp. 2d 193 ("[T]he Court cannot accept the

government's overly narrow and static definition of the product market."); *State of N.Y. v. Kraft Gen. Foods, Inc.*, 926 F. Supp. 321, 361 (S.D.N.Y. 1995) (rejecting plaintiff's more narrowly defined "adult cereal" market, finding "no principled basis for defining the relevant product market more narrowly than all [ready-to-eat] cereals.").

Response to Proposed Conclusion No. 20

This is not a proposed conclusion of law is incorrect because it rests on a faulty factual conclusion. As Complaint Counsel's Post-Trial Reply Brief explains, [redacted]

Moreover, for the reasons described in Response to Proposed Conclusion No. 13 the Proposed Conclusion is misleading and contrary to law. For these reasons, the Proposed Conclusion should be disregarded.

21. These non-NGS tests are too early in the development timeline to be included in the relevant market with Galleri. (PFF ¶ 693.1.) But if there were any merit to Complaint Counsel's approach to market definition (which sweeps in numerous tests that are in the early stages of development), then there is no reason to exclude them. What customers care about is whether a test works and for which indications, not how exactly it works. (PFF ¶ 696); *see, e.g.*, *Apartment Source*, 1999 WL 349938, at *23 (E.D. Pa. May 21, 1999) ("Even though the means used by these apartment communities to secure renters may not be identical substitutes for one another, they serve the same function and are used interchangeably"); *Telerate Systems, Inc. v. Caro*, 689 F. Supp. 221, 237–38 (S.D.N.Y. 1988) ("The first issue [of reasonable interchangeability] is "functional interchangeability"—the degree to which various products are able to perform the same *functions*") (emphasis added).

Response to Proposed Conclusion No. 21

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is vague as its unclear to which tests "[t]hese non-NGS tests" is referring. [redacted]

[redacted] For these reasons, the Proposed Conclusion should be disregarded.

2. **The Alleged Market Includes Products in Development That Are Not Reasonably Interchangeable**

22. The government's relevant market is also flawed because it fails to satisfy the test of reasonable interchangeability. A relevant product market consists of "products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325; *see du Pont*, 351 U.S. at 395. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function." *U.S. v. Microsoft Corp.*, 253 F.3d 34, 53–54 (D.C. Cir. 2001); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered).

Response to Proposed Conclusion No. 22

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Moreover, the Proposed Conclusion is misleading. When analyzing whether products are reasonably interchangeable, the purpose of market definition must be kept in mind: to illuminate the alleged anticompetitive effects. *Brown Shoe*, 370 U.S. at 325 ("Because § 7 of the Clayton Act prohibits any merger which may substantially lessen competition 'in *any* line of commerce', it is necessary to examine the effects of a merger in each such economically significant submarket to determine if there is a reasonable probability that the merger will substantially lessen competition.") (emphasis in original); *Horizontal Merger Guidelines* § 4 ((("The

measurement of market shares and market concentration is not an end in itself, but is useful to the extent it illuminates the merger's likely competitive effects."). Here Complaint Counsel has alleged that Respondents will have the ability and incentive to foreclose Grail's competitors in the research, development, and commercialization of MCED tests. Complaint ¶ 31. As such, MCED tests need to be sufficiently interchangeable (and customer substitution sufficiently likely) that the merged firm has an incentive to exercise its ability to foreclose, or otherwise disadvantage, the research, development, and commercialization of these tests as a result of the Acquisition. The immense evidence of current and future competition illustrates that Grail's rivals are sufficiently interchangeable to trigger the merged firm's incentive to disadvantage them in the race to gain market share in the research, development, and commercialization of MCED tests.

Microsoft was inapposite on this point. There, the D.C. Circuit was addressing the defendant's assertion that a product (middleware) might evolve so as to "overtake" the relevant product (Intel-compatible personal-computer operating systems) at some undefined point in the future. The court rejected that assertion and excluded middleware from the relevant market because it was not likely to do so at "any time in the near future." *United States v. Microsoft Corp.*, 253 F.3d 34, 54 (D.C. Cir. 2001). For the reasons stated above, the Proposed Conclusion should be disregarded.

23. "Interchangeability of use and cross-elasticity of demand look to the availability of products that are similar in character or use to the product in question and the degree to which buyers are willing to substitute those similar products for the product." *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 157 (D.D.C. 2000). "The first principle of market definition is substitutability: a relevant product market must 'identify a set of products that are reasonably interchangeable[.]'". *ProMedica Health Sys. v. FTC*, 749 F.3d 559, 565 (6th Cir. 2014) (quoting Horizontal Merger Guidelines § 4.1). "Chevrolets and Fords might be interchangeable in this sense, but Chevrolets and Lamborghinis are probably not." *Id.* (citing 2B Phillip E. Areeda, Herbert Hovenkamp & John L. Solow, Antitrust Law ¶ 533e at 259 (3d ed. 2007)). "The general question is whether two products can be used for the same purpose, and if so, whether and to

what extent purchasers are willing to substitute one for the other." *Arch Coal, Inc.*, 329 F. Supp. 2d at 119 (quotations omitted).

Response to Proposed Conclusion No. 23

The Proposed Conclusion is misleading and incomplete. When analyzing whether products are reasonably interchangeable, the purpose of market definition must be kept in mind: to illuminate the alleged anticompetitive effects. *Brown Shoe*, 370 U.S. at 325 ("Because § 7 of the Clayton Act prohibits any merger which may substantially lessen competition 'in *any* line of commerce', it is necessary to examine the effects of a merger in each such economically significant submarket to determine if there is a reasonable probability that the merger will substantially lessen competition.") (emphasis in original); *Horizontal Merger Guidelines* § 4 (("The measurement of market shares and market concentration is not an end in itself, but is useful to the extent it illuminates the merger's likely competitive effects."). Here Complaint Counsel has alleged that Respondents will have the ability and incentive to foreclose Grail's competitors in the research, development, and commercialization of MCED tests. Complaint ¶ 31. As such, MCED tests need to be sufficiently interchangeable (and customer substitution sufficiently likely) that the merged firm has an incentive to exercise its ability to foreclose, or otherwise disadvantage, the research, development, and commercialization of these tests as a result of the Acquisition. The immense evidence of current and future competition illustrates that Grail's rivals are sufficiently interchangeable to trigger the merged firm's incentive to disadvantage them in the race to gain market share in the research, development, and commercialization of MCED tests. For the reasons stated above, the Proposed Conclusion should be disregarded.

24. At present, there is no product in existence that is reasonably interchangeable with GRAIL's Galleri test. (PFF ¶ 697; *see, e.g., U.S. v. Microsoft Corp.*, 253 F.3d 34, 53–4 (D.C. Cir. 2001) (excluding middleware from the relevant market because "[w]hatever middleware's ultimate potential . . . consumers could not *now* abandon their operating systems and switch to

middleware"); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc*, 433 F. App'x 598, 599 (9th Cir. 2011) ("The failure to allege a product market consisting of reasonably interchangeable goods renders the complaint 'facially unsustainable'").)

Response to Proposed Conclusion No. 24

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Moreover, *United States v. Microsoft Corp.*, 253 F.3d 34, 53-4 (D.C. Cir. 2001) is inapposite for all the reasons described in Response to Proposed Conclusion No. 22. *Golden Gate* is similarly unavailing. Plaintiffs in *Golden Gate* failed to adequately plead a relevant market because they failed to allege the products were reasonably interchangeable. No. 4:16-CV-00350, 2010 WL 1541257, at *4 (N.D. Cal. Apr. 16, 2010). In contrast, Complaint Counsel has adduced a plethora of evidence supporting [redacted] For these reasons, the Proposed Conclusion should be disregarded.

25. Even if the tests in development were on the market, or could be expected to launch in the near term, Complaint Counsel failed to prove that any of these tests will be reasonably interchangeable with Galleri if and when they are launched. (PFF ¶ 708.) The purchasers of any MCED test will be patients, health care providers and/or insurers. (PFF ¶ 708.1.) Complaint Counsel did not call even a single medical expert, patient, health care provider or insurer to testify that he/she would substitute one of the tests in development (were it ever to be sold) for Galleri. (PFF ¶ 708.2.) Nor did Complaint Counsel conduct any surveys of such groups (PFF ¶ 708.3 (Complaint Counsel's expert "didn't attempt to fill those information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior.")—although such surveys are routinely done in healthcare markets. *See, e.g.*, *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 982–83 (N.D. Iowa 1995) (agreeing with defendants' relevant market based on survey results of patient preferences). Complaint Counsel also did not attempt to show the likely price of these tests. (PFF ¶¶ 750.1–750.4.) These are fatal flaws, especially where Complaint Counsel had ample power and authority to produce such a witness if there were any favorable to its case. *See Boardman v. Nat'l Med. Enterprises*, 106

F.3d 840, 844 (8th Cir. 1997) ("Drawing an adverse inference from the failure of a party to put on key witnesses relevant to some issue is most reasonable when it is the party with the burden of proof on that issue who fails to do so"); *Streber v. Comm'r*, 138 F.3d 216, 221–22 (5th Cir. 1998) ("In general, a court may draw a negative inference from a party's failure to produce a witness "whose testimony would elucidate the transaction") (citation and quotations omitted); *United States v. Lowe*, 234 F.2d 919, 923 (3d Cir. 1956) ("The rule is well known that as a general proposition when one fails to call a witness who might have something relevant to say about his case an unfavorable inference can be urged against the one who fails to call him.").

Response to Proposed Conclusion No. 25

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is also misleading to the extent it implies that Complaint Counsel needed to call a survey expert. The *Brown Shoe* factors (and market definition generally) are not nearly so rigid. Rather, Courts explain that the analysis must be guided by the ordinary course documents, *H&R Block*, 833 F. Supp. 2d at 52, and "take into account the realities of competition." *Fed. Trade Comm'n v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1039 (D.C. Cir. 2008) (citation omitted). Here, Respondents' ordinary course documents and the market realities show [redacted]

The Proposed Conclusion is also misleading and contrary to the law to the extent it seeks an adverse inference from Complaint Counsel's alleged failure to call a survey expert. As Respondents' own cases explain, an adverse inference may only be appropriate if the party seeking the adverse inference shows that the "witness was important and possessed relevant information." *Boardman v. Nat'l Med. Enterprises*, 106 F.3d 840, 844 (8th Cir. 1997). The witness must have information "peculiarly within his knowledge." *Streber v. C.I.R.*, 138 F.3d

216, 222 (5th Cir. 1998) (citation omitted); *United States v. Lowe*, 234 F.2d 919, 923 (3d Cir. 1956) (refusing to overturn jury verdict when defendant was asked in a former trial whether he called a particular witness). None of these cases indicate an adverse inference is appropriate here. First, Respondents have not identified a particular survey witness that possessed important and relevant information. Second, evidence of reasonable interchangeability is not particularly within any one person's knowledge. Indeed, Complaint Counsel has adduced a depth and breadth of evidence (including witness testimony) showing [redacted] For the reasons stated above, the Proposed Conclusion should be disregarded.

26. While Complaint Counsel points to instances where the test developers are termed "competitors", "the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes"; rather, market definition hinges on whether *consumers* view the products as reasonable substitutes. *FTC v. Sysco Corp*., 113 F. Supp. 3d 1, 26 (D.D.C. 2015) (emphasis added) (citations omitted); *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009) (holding that lay testimony and internal marketing documents "do[] not provide a sound economic basis for assessing the market . . . the way that a proper interchangeability test would."); *FTC v. Lundbeck, Inc.*, No. CIV. 08-6379 JNE/JJG, 2010 WL 3810015, at *20 (D. Minn. Aug. 31, 2010), *aff'd,* 650 F.3d 1236 (8th Cir. 2011) (rejecting FTC's proposed market definition consisting of both NeoProfen and Indocin IV despite internal company documents that refer to a market that consists of NeoProfen and Indocin IV); *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 498 (2d Cir. 2004) (finding that generic warfarin sodium alone constituted the relevant market even though "the industry undoubtedly acknowledges that Coumadin competes to some extent with generics").

Response to Proposed Conclusion No. 26

The Proposed Conclusion is misleading and contrary to the law. The cases Respondents cite to for this point are inapposite. None of their cases involved allegations of harm to a market for the research, development, and commercialization of a product, in which innovation is a critical axis of competition. *See FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 26 (D.D.C. 2015); *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009) (analyzing a Section 2 monopolization claim); *FTC v. Lundbeck, Inc.*, 2010 WL 3810015, at

*19-20 (D. Minn. Aug. 31, 2010) (analyzing whether Lundbeck's acquisition of drugs maintained its monopoly power resulting in price-based harm, where the government identified the wrong set of relevant market customers); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 498 (2d Cir. 2004) (analyzing whether competing chemical manufacturers violated Sections 1 and 2 of the Sherman Antitrust Act).

Moreover, Respondents mischaracterize Complaint Counsel's market definition analysis. Complaint Counsel looked at robust evidence of competition between Grail's Galleri test and other MCED tests, bolstered by Respondents' own documents, shows that Grail views its MCED rivals' tests as sufficiently developed to be head-to-head competitors, and thus reasonably interchangeable and part of the same product market. *See Bazaarvoice*, 2014 WL 203966, at *66 (holding that "Bazaarvoice's recognition that PowerReviews was its primary competitor supports the determination that R & R platforms are the relevant product market."); *see also In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 2118886, at *5-6 (F.T.C. May 6, 2019) (Chappell, A.L.J.) ("Market definition must take into account the realities of competition. Ordinary course of business documents reveal the contours of competition from the perspective of the parties, who may be presumed to have accurate perceptions of economic realities.") (internal quotations omitted). For the reasons stated above, the Proposed Conclusion should be disregarded.

3. Complaint Counsel's Alleged Market Runs Counter to the Supreme Court's *Brown Shoe* Factors

27. In addition to interchangeability of use and cross-elasticity of demand, courts look to the "practical indicia" set forth in *Brown Shoe* as guides for defining the relevant market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (examining "such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors").

Response to Proposed Conclusion No. 27

This is not a proposed conclusion of law because it does not expound on any legal

standard or proposition. Consequently, it should be disregarded.

The Proposed Conclusion also is incomplete. The relevant product market refers to the "product and services with which the defendants' products compete." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 193 (D.D.C. 2017) (internal quotations omitted). "Stated another way, a product market includes all goods that are reasonable substitutes, even though the products themselves are not entirely the same." *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 25 (D.D.C. 2015). The Supreme Court has identified a number of "practical indicia" that can indicate the existence of a relevant market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). As explained in Complaint Counsel's post-trial brief, an analysis of the *Brown Shoe* practical indicia show Complaint Counsel has properly defined a relevant market for the research, development, and commercialization of MCED tests. Complaint Counsel's Post-Trial Brief at 56-63. Specifically, as explained extensively throughout Complaint Counsel's initial briefing, an analysis of the following factors supports Complaint Counsel's defined market: peculiar characteristics and uses, distinct customers, distinct prices, and industry recognition of MCED tests as a separate market. Complaint Counsel's Post-Trial Brief at 56-63. For the reasons stated above, the Proposed Conclusion should be disregarded.

28. The *Brown Shoe* factors "are not to be used in a 'talismanic fashion' whereby their presence or absence are regarded as mechanically dispositive of the issue." *Kaplan v. Burroughs Corp.*, 611 F.2d 286, 292 (9th Cir. 1979) (citation omitted). Rather, they must be applied "pragmatically" to determine the existence of the "economically significant" product market. *Id.* (citations omitted).

Response to Proposed Conclusion No. 28

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded.

The Proposed Conclusion also is incomplete. The relevant product market refers to the "product and services with which the defendants' products compete." *United States v. Anthem,*

Inc., 236 F. Supp. 3d 171, 193 (D.D.C. 2017) (internal quotations omitted). "Stated another way, a product market includes all goods that are reasonable substitutes, even though the products themselves are not entirely the same." *FTC v. Sysco Corp*., 113 F. Supp. 3d 1, 25 (D.D.C. 2015). The Supreme Court has identified a number of "practical indicia" that can indicate the existence of a relevant market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). As explained in Complaint Counsel's post-trial brief, an analysis of the *Brown Shoe* practical indicia show Complaint Counsel has properly defined a relevant market for the research, development, and commercialization of MCED tests. Complaint Counsel's Post-Trial Brief at 56-63. Specifically, as explained extensively throughout Complaint Counsel's initial briefing, an analysis of the following factors supports Complaint Counsel's defined market: peculiar characteristics and uses, distinct customers, distinct prices, and industry recognition of MCED tests as a separate market. Complaint Counsel's Post-Trial Brief § II.B.1. For the reasons stated above, the Proposed Conclusion should be disregarded.

29. To the extent there is sufficient evidence to properly apply the *Brown Shoe* indicia, they point to a relevant product market consisting only of Galleri, not Galleri and a number of uncertain and unfinished potential tests in development that lack, and cannot plausibly develop in the foreseeable future, the distinctive features of Galleri. *See Microsoft*, 253 F.3d at 53–54 (stating that the test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function"); *Epic Games, Inc. v. Apple Inc.*, No. 4:20–CV-05640–YGR, 2021 WL 4128925, at *56 (N.D. Cal. Sept. 10, 2021) (excluding Nintendo and other gaming services from the market because they were "too new" to determine "whether consume[r]s will or do consider these products reasonably interchangeable").

Response to Proposed Conclusion No. 29

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, the Proposed Conclusions rests on record evidence with no corresponding citations as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion also is incomplete, misleading, and contrary to the law. The relevant product market refers to the "product and services with which the defendants' products compete." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 193 (D.D.C. 2017) (internal quotations omitted). "Stated another way, a product market includes all goods that are reasonable substitutes, even though the products themselves are not entirely the same." *FTC v. Sysco Corp*., 113 F. Supp. 3d 1, 25 (D.D.C. 2015). The Supreme Court has identified a number of "practical indicia" that can indicate the existence of a relevant market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). As explained in Complaint Counsel's post-trial brief, an analysis of the *Brown Shoe* practical indicia show Complaint Counsel has properly defined a relevant market for the research, development, and commercialization of MCED tests. Complaint Counsel's Post-Trial Brief at 56-63. Specifically, as explained extensively throughout Complaint Counsel's initial briefing, an analysis of the following factors supports Complaint Counsel's defined market: peculiar characteristics and uses, distinct customers, distinct prices, and industry recognition of MCED tests as a separate market. Complaint Counsel's Post-Trial Brief at 56-63.

Moreover, *Microsoft*, 253 F.3d at 53–54 and *Epic Games, Inc. v. Apple Inc.*, WL 4128925, are inapposite for all the reasons described in Complaint Counsel's Response to Proposed Conclusions No. 16 and No. 22. For the reasons stated above, the Proposed Conclusion should be disregarded.

a. No industry or public recognition of the alleged market as a separate economic entity

30. The "industry or public recognition" factor is one that concerns "observations about what one ordinarily observes when a market is distinct" and "matters because we assume that economic actors usually have accurate perceptions of economic realities." *Rothery*, 792 F.2d at 218 n.4.

Response to Proposed Conclusion No. 30

The Proposed Conclusion is incomplete and should be disregarded. The "industry recognition" prong assesses whether industry actors treat the industry as a market. *Peabody*, 492 F. Supp. at 895; *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 53 (D.D.C. 2011) ("[E]vidence of industry or public recognition of the submarket as a separate economic unit matters because we assume that economic actors usually have accurate perceptions of economic realities.").

31. Neither the industry nor the public recognizes an MCED market *as defined by Complaint Counsel*. Courts have declined to recognize a proposed market as a separate economic entity even where there was greater industry or public recognition than there is here. *See, e.g., Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 616 (8th Cir. 2011) (declining to recognize the hospital's proposed market despite evidence of industry recognition from hospital documents, statements by other industry executives and contracts); *Ky. Speedway*, 588 F.3d at 919 (holding that lay testimony and internal marketing documents "do[] not provide a sound economic basis for assessing the market . . . the way that a proper interchangeability test would."); *Geneva Pharms. Tech.*, 386 F.3d at 496 (refusing to recognize a market of generic warfarin sodium and Coumadin although "the industry undoubtedly acknowledges that Coumadin competes to some extent with generics"); *Lundbeck*, No. CIV. 08-6379 JNE/JJG, 2010 WL 3810015, at *20 (rejecting FTC's proposed market definition consisting of both NeoProfen and Indocin IV despite internal company documents that refer to a market that consists of NeoProfen and Indocin IV).

Response to Proposed Conclusion No. 31

The Proposed Conclusion is contrary to the law and misleading. With one exception, Respondents' cases all involve Section 2 of the Sherman Act, which incorporates a different legal standard for liability. *Ky. Speedway, LLC v. National Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009); *Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 614-16 (8th Cir. 2011) (analyzing the requirements of a submarket in a Section 2 case); *FTC v. Lundbeck, Inc.*, 2010 WL 3810015, *1 (D. Minn. 2010) (analyzing Section 2 in part). Congress intended Section 7 to have a lower standard than the Sherman Act for judging the legality of business combinations, and as such this case is inapposite. *Brown Shoe*, 370 U.S. at 318 ("Congress rejected, as inappropriate to the problem it sought to remedy, the application to § 7 cases of the

standards for judging the legality of business combinations adopted by the courts in dealing with cases arising under the Sherman Act, and which may have been applied to some early cases arising under original § 7."). *Geneva Pharms. Tech.* also is not probative given the extent of evidence of competition between MCED test developers in the record. 386 F.3d at 496. Moreover, Complaint Counsel introduced extensive evidence of industry recognition of the MCED market. Complaint Counsel's Post-Trial Reply Brief at 36-38. For the reasons stated above, the Proposed Conclusion should be disregarded.

b. The products' peculiar characteristics and uses

32. "The 'product's peculiar characteristics' refers to the general truth that substitutes in a market often have a strong physical and functional relationship". *Rothery Storage*, 792 F.2d at 218 n.4. A product or group of products constitutes a distinct market when it has "(sufficient) peculiar characteristics and uses which make it distinguishable from all other products". *United States v. Brown Shoe Co.*, 179 F. Supp. 721, 729 (E.D. Mo. 1959), *aff'd*, 370 U.S. 294 (1962) (quotations omitted). The peculiar characteristics and uses of Galleri and the MCED tests in development place them in different relevant markets.

Response to Proposed Conclusion No. 32

The Proposed Conclusion is misleading and incomplete. "A product market includes all goods that are reasonable substitutes, even where the products are not entirely the same." *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 117 (D.D.C. 2016). The Proposed Conclusion is misleading to the extent it implies that the products are too differentiated to be reasonable substitutes.

An accurate comparison shows that MCED test developers are all in the process of developing tests that share the same core features. MCED developers intend to detect the presence and location of multiple (not merely one, two, or three) types of cancers in asymptomatic patients through a blood draw. (CCFF ¶¶ 1902-2606). Respondents' attempts to mischaracterize other MCED tests is supported only by out-of-context testimony and is against the overwhelming weight of the evidence. (Response to RPFF ¶¶ 730, 730.1, 730.2, 730.3, 730.4, 730.5, 731, 731.1, 731.2, 731.3, 732, 732.3, 732.4, 733, 733.2, 734, 735). For the reasons

stated above, the Proposed Conclusion should be disregarded.

33. Products have been placed in separate antitrust markets based on differences in characteristics and uses that are less pronounced than the differences between the characteristics and uses of Galleri and other MCED tests in development. *See, e.g.*, *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 302 n.15 (D.D.C. 2020) (separating hydrogen peroxide into distinct markets based on their end uses because "end uses within standard grade, by their definition, have 'peculiar characteristics and uses'"); *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 23 (D.D.C. 2017) (placing Medicare Advantage and Original Medicare into distinct markets due to distinct characteristics of Medicare Advantage, such as limited out-of-pocket expenses and supplemental benefits).

Response to Proposed Conclusion No. 33

The Proposed Conclusion is misleading and incomplete. "A product market includes all goods that are reasonable substitutes, even where the products are not entirely the same." *Staples*, 190 F. Supp. 3d at 117. Respondents' cited cases are inapposite. *Federal Trade Commission v. RAG-Stiftung*, 436 F. Supp. 3d 278, 302 n.15 (D.D.C. 2020), discusses types of hydrogen peroxide that have different uses. In contrast, here, an accurate comparison shows that MCED test developers are all in the process of developing tests that share the same core features. MCED developers intend to detect the presence and location of multiple (not merely one, two, or three) types of cancers in asymptomatic patients through a blood draw. (CCFF ¶¶ 1902-2606). Respondents' attempts to mischaracterize other MCED tests is supported only by out-of-context testimony and is against the overwhelming weight of the evidence. (Response to RPFF ¶¶ 730, 730.1, 730.2, 730.3, 730.4, 730.5, 731, 731.1, 731.2, 731.3, 732, 732.3, 732.4, 733, 733.2, 734, 735).

United States v. Aetna Inc. does not counsel otherwise. 240 F.Supp.3d 1, *23, *29 (D.D.C. 2017). The court in *Aetna, Inc.* held that despite the fact that both Original Medicare and Medicare Advantage serve the same function—to provide Medicare benefits to seniors—the other *Brown Shoe* factors counseled towards a separate submarket for Medicare Advantage. *Id.* at *23-*29. Here an application of the other *Brown Shoe* practical indicia also supports an

MCED market. For the reasons stated above, the Proposed Conclusion should be disregarded.

c. Unique production facilities

34. "The cross-elasticity of production facilities may also be an important factor in defining a product market." *Brown Shoe*, 370 U.S. at 325, n.42. "If a product requires unique production facilities, and the producer raises the price above the competitive level, the ability of other producers to shift resources to make the product would be limited, and the market definition should be likewise limited." *Rothery Storage*, 792 F.2d at 219 n.4; *see also IGT v. All. Gaming Corp.*, 702 F.3d 1338, 1347 (Fed. Cir. 2012) ("[T]here are no unique production facilities or specialized vendors for wheel games versus ordinary gaming machines; one can just as easily produce a gaming machine with a square bonus as one with a circular bonus."). Courts are more likely to find that two products are in separate antitrust markets under this factor if they have a need for specialized technology. *See Epic Games*, 2021 WL 4128925, at *42 (excluding non-game apps from the market of game apps as "game developers often use specialized technology to create their apps" and "tend to specialize in the development of game apps and related gaming software").

Response to Proposed Conclusion No. 34

The Proposed Conclusion is incomplete and misleading. Unique production facilities can help to indicate a relevant market. *Brown Shoe Co.*, 385 U.S. at 325; *FTC v. Peabody Energy Corp.*, 492 F. Supp. 3d 865, 900 (E.D. Mo. 2020) ("It is even easier [in this case] for the FTC to satisfy the 'unique production facilities' prong of *Brown Shoe*."). Respondents misapply this factor by not analyzing the differences in production facilities but rather in the production process, arguing that the use of "specialized technology" shows that they are not in the same market. Remarkably, Respondents fail to address the one piece of "specialized technology" that the MCED tests all have in the common: the use of NGS technology. (CCFF ¶¶ 886-1901). If anything, then, this "practical indicia" lends additional support for defining a market that includes Respondents' MCED test with other MCED tests. Of course, the presence or absence of any single *Brown Shoe* indicia is not by itself outcome-determinative as to market definition in this case. *International Tel. & Tel. Corp. v. General Telephone & Electronics Corp.*, 518 F.2d 913, 932-33 (9th Cir. 1975) ("These indicia were listed with the intention of furnishing practical aids in identifying zones of actual or potential competition rather than with the view that their

presence or absence would dispose, in talismanic fashion, of the submarket issue. Whether or not a court is justified in carving out a submarket depends ultimately on whether the factors which distinguish one purported submarket from another are 'economically significant' in terms of the alleged anticompetitive conduct."). For these reasons, the Proposed Conclusion should be disregarded.

35. GRAIL's use of "specialized technology" distinct from the other putative MCED test developers demonstrates that Galleri and these putative tests in development do not belong in the same market. *See Epic Games*, 2021 WL 4128925, at *42. In any event, Complaint Counsel has not shown there to be cross-elasticity of production facilities between Galleri and the putative MCED tests in development to merit including them in the same market. *See Brown Shoe*, 370 U.S. at 325, n.42; *Rothery Storage*, 792 F.2d at 219 n.4.

Response to Proposed Conclusion No. 35

The Proposed Conclusion is misleading and incomplete for the reasons described in Response to Proposed Conclusion No. 34. In *Epic Games*, the Court held that "game developers use specialized technology to create their game apps. For example, specialized middleware tools like the Unity engine and Epic Games' *Unreal Engine* are primarily used by game developers. 559 F.Supp. 3d 898. Like MCED customer all rely on Illumina's NGS sequencer—indicating the Complaint Counsel has properly defined the market. (CCFF § V). For these reasons, the Proposed Conclusion should be disregarded.

d. Distinct customers

36. A finding that a product has distinct customers "may indicate unique product attributes, which refers again to the fact that products with distinct physical and functional attributes tend to be priced differently." *Rothery Storage*, 792 F.2d at 218 n.4. "[W]hen one or a few firms differentiate themselves by offering a particular package of goods or services, it is quite possible for there to be a central group of customers for whom only [that package] will do." *United States v. Grinnell Corp.*, 384 U.S. 563, 574 (1966). A core group of distinct customers may constitute a distinct market "because they find a particular product uniquely attractive". *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 112 (1984).

Response to Proposed Conclusion No. 36

The Proposed Conclusion is misleading in that it misapplies this *Brown Shoe* factor. As

[redacted] ([redacted]). To the extent that an MCED test has unique features that some customers prefer over another test's features, it does not indicate that these tests are not in the same market, but rather is a facet of competition that this case seeks to protect. *FTC v. R.R. Donnelley & Sons Co.*, 1990 WL 193674, at *2 (D.D.C. 1990) ("Products or services need not be fungible to be considered within the same market."). The cited portion of *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla.* does not discuss relevant market but rather whether defendants in that case have market power. 468 U.S. 85, 112 (1984). For these reasons, the Proposed Conclusion should be disregarded.

e. Distinct prices

37. Products with distinct prices "suggest[] that cross-elasticity of demand is low", *Rothery Storage*, 792 F.2d at 218 n.4, and should be placed in different antitrust markets. *Reynolds Metals Co. v. FTC,* 309 F.2d 223, 229 (D.C. Cir. 1962). The "distinct prices" inquiry is quantitative, as it "goes directly to the economic criteria that make one market distinct from another." *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 985–86 (C.D. Cal. 2012).

Response to Proposed Conclusion No. 37

The Proposed Conclusion is incomplete and misleading. Respondents once again misapply the *Brown Shoe* factors, as well as misstate the evidence in this case. When analyzing this factor, courts assess whether defendants analyze the prices of competitors when competing for business. *See, e.g.*, *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 30 (D.D.C. 2015) ("Broadliners generally compete only against other broadliners on pricing."). [redacted]

[redacted] Respondents' assertion otherwise is based on misleading citations taken out of context. For example, Respondents selectively quote Guardant's Vice President of Commercial William Getty as testifying that "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price." However, that statement is immediately followed by Getty clarifying: "[b]ut ultimately the ability to compete on price is always there when you have folks who are paying for the test . . . and want to pay the lowest cost." *Compare* (PX7105 (Getty (Guardant) Dep. at 106–07) *with* (RPFF ¶ 748). [redacted] For these reasons, the Proposed Conclusion should be disregarded**.**

f. Sensitivity to price changes

38. ""If a slight decrease in the price of product A causes a considerable number of customers of product B to switch to A, that would indicate that a cross-elasticity of demand exists between A and B and that they compete in the same product market." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 120 (D.D.C. 2004). Therefore, courts should "exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn." *Id.* (quoting *Times–Picayune Publ'g Co. v. United States,* 345 U.S. 594, 612 n. 31 (1953)).

Response to Proposed Conclusion No. 38

The Proposed Conclusion is misleading and incomplete for all the reasons described in Complaint Counsel's Response to Proposed Conclusion No. 37, and should be disregarded.

39. Where, as here, a plaintiff cannot show price sensitivity based on an appropriate economic analysis, courts regularly find that a plaintiff cannot meet its burden to prove a relevant market, even in instances where the plaintiff has presented more than Complaint Counsel here--for example, survey evidence. *See, e.g.*, *Se. Mo. Hosp.*, 642 F.3d at 616 (finding that the plaintiff failed to prove a relevant market because the expert asserted that customers were not sensitive to price changes but offered "no market studies to support this claim, making the assertion without analytic or even anecdotal evidence"); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 664 (7th Cir. 2004) (finding that the plaintiff failed to prove that at-shelf dispensers were a relevant market because he "introduced no econometric evidence of any kind" and instead "offered a potpourri of survey research and armchair economics"); *Thurman Indus., Inc. v. Pay 'N' Pak Stores, Inc.*, 875 F.2d 1369, 1376 (9th Cir. 1989) (rejecting the plaintiff's proposed market because mere assertions of consumer preferences were "wholly inadequate to allow a finding" of a lack of price sensitivity); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc*., 7 F.3d 986, 997 (11th Cir. 1993) (rejecting the plaintiff's proposed market for providing "no basis other than guesswork" for concluding that consumers would be sensitive to price changes); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993) (rejecting market definition where expert's opinion based on "limited anecdotal evidence" and "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or comparative features of other competing products").

Response to Proposed Conclusion No. 39

The Proposed Conclusion is misleading, incomplete, and contrary to the law. Respondents also imply that Complaint Counsel has not met its burden to define and prove a relevant market because it has failed to provide survey information showing price. Resp. Post-Tr. Br. at 61. The *Brown Shoe* factors (and market definition generally) are not nearly so rigid. Rather, Courts explain that the analysis must be guided by the ordinary course documents, *H&R Block*, 833 F. Supp. 2d at 52, and "take into account the realities of competition." *Whole Foods*, 548 F.3d at 1039. [redacted] Respondents' cases are inapposite as each case rejected plaintiff's market definition when it rested on substantially less evidence than this case. *See, e.g.*, *Se. Missouri Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 616 (8th Cir. 2011) ("Saint Francis's expert, however, offers no market studies to support this claim, making the assertion without analytic or even anecdotal evidence."); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 664

(7th Cir. 2004) (explaining that "Menasha introduced no econometric evidence of any kind," and instead "offered a potpourri of survey research and armchair economics."); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc*., 7 F.3d 986, 997 (11th Cir. 1993) (rejecting the plaintiff's proposed market after an application of the *Brown Shoe* practical indicia and economic evidence); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir.1993) ("There was no detailed examination of market data or any analysis of cost, comparable usage, or comparative features of other competing products.").

g. Specialized vendors

40. Finally, specialized vendors "may indicate unique product attributes, which refers again to the fact that products with distinct physical and functional attributes tend to be priced differently." *Rothery Storage*, 792 F.2d at 219 n.4. A product has specialized vendors when it has "avenues for distribution . . . which differ[] in both kind and degree". *Epic Games*, 2021 WL 4128925, at *42.

Response to Proposed Conclusion No. 40

The Proposed Conclusion is misleading and incomplete. Respondents misapply this *Brown Shoe* practical indicia. [redacted] Hans Bishop—Grail's former CEO—admitted at trial that any positive diagnosis will require "diagnostic confirmation" through either a tissue biopsy or through PET-CT scan. (Bishop (Grail) Tr. 1387). [redacted] For these reasons, the Proposed Conclusion

should be disregarded.

41. Products are routinely held to fall in different markets where they are sold by specialized vendors or distributed differently. *Epic Games,* , 2021 WL 4128925, at *42 (separating game apps from the non-game apps market because "game apps have multiple avenues for distribution," which "differ[] in both kind and degree from those available to non-gaming apps" and are "specifically designed for such games—and not non-gaming apps").

Response to Proposed Conclusion No. 41

The Proposed Conclusion is misleading and incomplete to the extent that Respondents misapply this prong of the *Brown Shoe* test, as explained in Complaint Counsel's Response to Proposed Conclusion No. 40 and in Complaint Counsel's post-trial briefing. Therefore, the Proposed Conclusion should be disregarded.

42. The *Brown Shoe* factors point decidedly against the FTC's alleged market. *See, e.g.*, *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 302 n.15 (D.D.C. 2020) (rejecting the FTC's proposed market of standard grade hydrogen peroxide because the Brown Shoe factors pointed to a narrower market based on the "peculiar characteristics and uses" of hydrogen , the customers that "tend to be different" but still overlap, and the distinct prices); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (rejecting the plaintiff's proposed market because of insufficient evidence of price sensitivity and countervailing evidence of a different market due to its distinct customers).

Response to Proposed Conclusion No. 42

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, the Proposed Conclusion is incorrect and contrary to the weight of the evidence. As explained in detail in Complaint Counsel's post-trial briefing, an analysis of the *Brown Shoe* practical indicia show Complaint Counsel has properly defined a relevant market for the research, development, and commercialization of MCED tests. *See* Complaint Counsel's Post-Trial Brief § II.B.1; Complaint Counsel's Post-Trial Reply Brief § I.B.2. Therefore, the Proposed Conclusion should be disregarded.

4. The Alleged Market Fails the Hypothetical Monopolist Test

43. In addition to the *Brown Shoe* practical indicia, courts (and the Commission) sometimes rely on the approach set forth in the Merger Guidelines to define the relevant product

market–the hypothetical monopolist test. *See, e.g., Staples*, 190 F. Supp. 3d at 121–22; *Sysco*, 113 F. Supp. 3d at 33–34; *ProMedica*, 2012 FTC LEXIS 293, at *40–41 (citations omitted); *Polypore*, 2010 WL 9549988 at *11, *15. That test asks whether a hypothetical monopolist of a particular group of substitute products could profitably impose a "small but significant and non-transitory increase in price" ("SSNIP"), typically five percent, on at least one of the products in the candidate market, including at least one product sold by one of the merging firms. Merger Guidelines §§ 4.1.1–4.1.3. "If enough consumers are able to substitute away from the hypothetical monopolist's product to another product and thereby make a price increase unprofitable, then the relevant market cannot include only the monopolist's product and must also include the substitute goods. On the other hand, if the hypothetical monopolist could profitably raise price by a small amount, even with the loss of some customers, then economists consider the monopolist's product to constitute the relevant market." *Sysco*, 113 F. Supp. 3d at 33. The hypothetical monopolist test is typically based on prices that would "likely prevail absent the merger" or, if prices are likely to change absent the merger, the test may use "anticipated future prices". Merger Guidelines § 4.1.2.

Response to Proposed Conclusion No. 43

The Proposed Conclusion is incomplete and misleading to the extent it suggestions that the hypothetical monopolist test must involve prices. Along with the practical indicia set out in *Brown Shoe*, courts commonly use the hypothetical monopolist test to assess the relevant product market. *See FTC v. Advocate Health Care Network*, 841 F.3d 460, 468-69 (7th Cir. 2016) (applying the hypothetical monopolist test to define a relevant geographic market); *see also Penn State Hershey*, 838 F.3d at 338; *In re ProMedica Health Sys., Inc.*, 2012 WL 1155392, at *14 (F.T.C. Mar. 28, 2012); *Sysco*, 113 F. Supp. 3d at 33-34; *H&R Block*, 833 F. Supp. 2d at 51-52; *Horizontal Merger Guidelines* § 4.1.1. Under the hypothetical monopolist test, a candidate market constitutes a relevant antitrust market if a hypothetical monopolist could profitably impose a "small but significant and non-transitory increase in price" ("SSNIP"), or reduce quality or availability, on at least one product of the merging parties in the candidate market, or whether customers switching to alternative products would make such a price increase unprofitable. *See Horizontal Merger Guidelines* § 4.1.1; *see also Otto Bock*, 2019 WL 2118886, at *6 (Chappell, A.L.J.). Applied here, the test would ask whether a hypothetical monopolist owning Grail's Galleri test and all other third-party MCED tests could profitably impose a

SSNIP, or a reduction in test quality or availability, on one of the tests; if it could, then MCED Tests would constitute a relevant product market.

The Proposed Conclusion is misleading to the extent it suggests that the economic analysis of a relevant product market must involve pricing data. [redacted] Indeed, Respondents cite no case that requires plaintiffs to conduct a "quantitative SSNIP" test or otherwise to analyze price changes or survey data. Resp. Post-Tr. Br. at 65. To the contrary, "Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one. This is because [t]he market, as most concepts in law or economics cannot be measured by metes and bounds." *Anthem*, 236 F. Supp. 3d at 193 (internal citations omitted). Contrary to Respondents' assertions, an economic expert's opinion does not need to be based on quantitative information to be probative. *See, e.g.*, *Phila. Nat'l Bank*, 374 U.S. at 362; *H & R Block*, 833 F. Supp. 2d at 88 (finding that an expert's opinion (even when limited by lack of data) can be helpful to corroborate other evidence in the record like "documents, testimony, and other evidence"); *Aetna*, 240 F. Supp. 3d at 47 (finding that Plaintiff's expert supported the predicted harm that "the merged firm would have the incentive and ability to increase [prices]"); *Sysco*, 113 F. Supp. 3d at 37. Moreover, requiring such a heightened standard would effectively create a safe harbor from antitrust enforcement for companies in industries where pricing data is unavailable in contravention of the plain language of the Clayton Act. 15 U.S.C. § 18. Therefore, the Proposed

Conclusion should be disregarded.

44. As described in the Findings of Fact, Complaint Counsel's expert did not conduct a SSNIP analysis based on quantitative purchase data, did not examine data describing past purchase patterns of consumers and their responses to price changes, did not consider any normal course of business documents describing how Galleri customers responded to a price increase, and did not consider any normal course business documents describing how any MCED test customer would respond to a price increase. *See In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 985; *see also Se. Mo. Hosp.*, 642 F.3d at 616 (rejecting expert conclusion that a SSNIP in the relevant market would not cause customers to switch when there were "no market studies to support [the] claim" and the "assertion [was] without analytic or even anecdotal evidence."); *Vollrath*, 9 F.3d at 1462 (rejecting market definition where expert's opinion based on "limited anecdotal evidence" and "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or comparative features of other competing products."); *Reifert*, 450 F.3d at 318, 320 (requiring that "a plaintiff prove that products are good substitutes *using economic evidence*; a conclusory assumption of competition where products or services appear to be similar is insufficient.") (emphasis added).

Response to Proposed Conclusion No. 44

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is incorrect, contrary to the law, and misleading to the extent it implies a SSNIP analysis must be based on quantitative purchase data, past purchase patterns, or responses to price changes. [redacted] Indeed, Respondents cite no case that requires plaintiffs to conduct a "quantitative SSNIP" test or otherwise to analyze price changes or survey data. Resp. Post-Tr. Br. at 65. To the contrary, "Congress prescribed a pragmatic, factual

approach to the definition of the relevant market and not a formal, legalistic one. This is because [t]he market, as most concepts in law or economics cannot be measured by metes and bounds." *Anthem*, 236 F. Supp. 3d at 193 (internal citations omitted). Contrary to Respondents' assertions, an economic expert's opinion does not need to be based on quantitative information to be probative. *See, e.g., Phila. Nat'l Bank*, 374 U.S. at 362; *H & R Block*, 833 F. Supp. 2d at 88 (finding that an expert's opinion (even when limited by lack of data) can be helpful to corroborate other evidence in the record like "documents, testimony, and other evidence"); *Aetna*, 240 F. Supp. 3d at 47 (finding that Plaintiff's expert supported the predicted harm that "the merged firm would have the incentive and ability to increase [prices]"); *Sysco*, 113 F. Supp. 3d at 37. Moreover, requiring such a heightened standard would effectively create a safe harbor from antitrust enforcement for companies in industries where pricing data is unavailable in contravention of the plain language of the Clayton Act. 15 U.S.C. § 18.

The cases Respondents cite are inapposite. The first case Respondents cite confirms the probative value of Dr. Scott Morton's analysis. *See In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 986 (C.D. Cal. 2012) ("[T]he Court assumes that an expert economist may, under appropriate circumstances, define the relevant product market through an entirely qualitative assessment of the 'practical indicia' identified in *Brown Shoe*."). The other cases are equally unavailing. None of the cited cases state that an economist's qualitative assessment of the market is not probative. Rather, the cited cases simply say the weight of the evidence did not support the economist's testimony. *See Se. Missouri Hosp.*, 642 F.3d 608, 616 (8th Cir. 2011); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993). [redacted]

[redacted] This Proposed Conclusion should be disregarded.

45. Complaint Counsel's expert purports to have conducted a SSNIP test using qualitative data but this analysis consists of nothing more than a thought exercise in which she weighed the evidence shown to her by her staff and Complaint Counsel, and pronounced that the hypothetical monopolist test is satisfied. That is not permissible expert testimony. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("Expert testimony is useful as a guide to interpreting market facts, but it is not a substitute for them."); *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1435–36 (9th Cir. 1995) ("In the context of antitrust law, if there are undisputed facts about the structure of the market that render the inference economically unreasonable, the expert opinion is insufficient to support [a finding of fact].").

Response to Proposed Conclusion No. 45

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is incorrect, misleading, and contrary to the weight of the evidence to the extent it implies that [redacted] Indeed, Respondents cite no case that requires plaintiffs to conduct a "quantitative SSNIP" test or otherwise to analyze price changes or survey data. Resp. Post-Tr. Br. at 65. To the contrary, "Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one. This is because [t]he market, as most concepts in law or economics cannot be measured by metes and bounds." *Anthem*, 236 F. Supp. 3d at 193 (internal citations

omitted). Contrary to Respondents' assertions, an economic expert's opinion does not need to be based on quantitative information to be probative. *See, e.g.*, *Phila. Nat'l Bank*, 374 U.S. at 362; *H & R Block*, 833 F. Supp. 2d at 88 (finding that an expert's opinion (even when limited by lack of data) can be helpful to corroborate other evidence in the record like "documents, testimony, and other evidence"); *Aetna*, 240 F. Supp. 3d at 47 (finding that Plaintiff's expert supported the predicted harm that "the merged firm would have the incentive and ability to increase [prices]"); *Sysco*, 113 F. Supp. 3d at 37. Moreover, requiring such a heightened standard would effectively create a safe harbor from antitrust enforcement for companies in industries where pricing data is unavailable in contravention of the plain language of the Clayton Act. 15 U.S.C. § 18.

The Proposed Conclusion is incorrect and misleading to the extent it implies that [redacted] As Respondents themselves admit, "[e]xpert testimony is useful as a guide to interpreting market facts." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993); *see also, e.g.*, *Philadelphia Nat'l Bank*, 374 U.S. at 362; *H & R Block*, 833 F. Supp. 2d at 88; *Aetna*, 240 F. Supp. 3d at 46; *Bazaarvoice*, 2014 WL 203966, at *32. This Proposed Conclusion should be disregarded.

46. In any case, courts will typically reject an expert's "proposed product market definition [based] entirely upon his qualitative assessment of the market, without any supporting quantitative economic analysis." *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 985; *see also Se. Mo. Hosp.*, 642 F.3d at 616 (rejecting expert conclusion that a SSNIP in the relevant

market would not cause customers to switch when there were "no market studies to support [the] claim" and the "assertion [was] without analytic or even anecdotal evidence."); *Reifert*, 450 F.3d at 318, 320 ("While the 'practical indicia' named in *Brown Shoe* . . . are important considerations in defining a market, they were never intended to exclude economic analysis altogether"); *ABS Glob., Inc. v. Inguran, LLC*, No. 14–CV-503–WMC, 2016 WL 3963246, at *14 (W.D. Wis. July 21, 2016) ("[This] Circuit has repeatedly emphasized the need for both a quantitative and qualitative economic analysis in arriving at a market definition"); *Vollrath*, 9 F.3d at 1462 (rejecting market definition where "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or comparative features of other competing products."); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1145–49 (N.D. Cal. 2004) (expert included significant, specific, and extensive analysis of the factors thought to be relevant to making a hypothetical claim based on an SSNIP). Imagining a scenario in which the SSNIP test might be satisfied is not the same thing as proving it, especially where, as here, Dr. Scott Morton did not attempt to fill the information gaps using surveys or other means, did not attempt to analyze substitution from the perspective of payors and did not attempt to use the limited available information about the possible characteristics of the tests to assess whether switching is likely within her defined market. (PFF ¶ 767.) Using "qualitative evidence" is no different than doing a market definition analysis using the *Brown Shoe* factors—which the alleged market does not satisfy for the reasons discussed above.

Response to Proposed Conclusion No. 46

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is incorrect, misleading, and contrary to the weight of the evidence to the extent it implies that [redacted] Indeed, Respondents cite no case that requires plaintiffs to conduct a

"quantitative SSNIP" test or otherwise to analyze price changes or survey data. Resp. Post-Tr. Br. at 65. To the contrary, "Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one. This is because [t]he market, as most concepts in law or economics cannot be measured by metes and bounds." *Anthem*, 236 F. Supp. 3d at 193 (internal citations omitted). Contrary to Respondents' assertions, an economic expert's opinion does not need to be based on quantitative information to be probative. *See, e.g.*, *Phila. Nat'l Bank*, 374 U.S. at 362; *H & R Block*, 833 F. Supp. 2d at 88 (finding that an expert's opinion (even when limited by lack of data) can be helpful to corroborate other evidence in the record like "documents, testimony, and other evidence"); *Aetna*, 240 F. Supp. 3d at 47 (finding that Plaintiff's expert supported the predicted harm that "the merged firm would have the incentive and ability to increase [prices]"); *Sysco*, 113 F. Supp. 3d at 37. Moreover, requiring such a heightened standard would effectively create a safe harbor from antitrust enforcement for companies in industries where pricing data is unavailable in contravention of the plain language of the Clayton Act. 15 U.S.C. § 18.

The cases Respondents cite are inapposite. The first case Respondents cite confirms the probative value of Dr. Scott Morton's analysis. *See In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 986 (C.D. Cal. 2012) ("[T]he Court assumes that an expert economist may, under appropriate circumstances, define the relevant product market through an entirely qualitative assessment of the 'practical indicia' identified in *Brown Shoe*."). The other cases are equally unavailing. None of the cited cases state that an economist's qualitative assessment of the market is not probative. Rather, the cited cases simply say the weight of the evidence did not support the economist's testimony. *See Se. Missouri Hosp.*, 642 F.3d 608, 616 (8th Cir. 2011); *ABS Glob., Inc. v. Inguran, LLC*, No. 14-CV-503, 2016 WL 3963246, at *14 (W.D. Wis. July

21, 2016); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1145-49 (N.D. Cal. 2004). For example, in *Reifert v. South Cent. Wisconsin MLS Corp.*, 450 F.3d 312, 318 (7th Cir. 2006), the court did not require that quantitative analysis, but rather "data and a reasonable analysis." [redacted] This Proposed Conclusion should be disregarded.

47. Complaint Counsel's expert opinion does not "incorporate all aspects of the economic reality" of the relevant market, amounts to "mere speculation", and therefore should not be admitted. *Concord Boat*, 207 F.3d at 1057.

Response to Proposed Conclusion No. 47

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded. Concord Boat is inapposite.

Moreover, as explained extensively throughout Complaint Counsel's post-trial briefing (and unlike in Concord Boat), Dr. Scott Morton's analysis conducts an extensive review of "all aspects of the economic reality." *See, e.g.*, Complaint Counsel's Post-Trial Brief at I.B.2.vi

48. Defining a relevant product market generally requires a detailed examination of "market data, figures or other relevant material adequately describing the nature, cost, usage or other features of competing products." *Grason Elec. Co. v. Sacramento Mun. Util. Dist.*, 571 F. Supp. 1504, 1521 (E.D. Cal. 1983) (quoting *Morton Bldgs. of Neb. Inc. v. Morton Bldgs., Inc.,* 531 F.2d 910, 919 (8th Cir. 1976). "Expert testimony that is speculative is not competent proof and contributes nothing to a legally sufficient evidentiary basis." *Concord Boat*, 207 F.3d at 1057. (internal citations and quotations omitted). Thus, Dr. Scott Morton's market definition opinions should be disregarded.

Response to Proposed Conclusion No. 48

The Proposed Conclusion is incorrect, contrary to the law, and misleading to the extent it

implies an expert's relevant market analysis must rely on "market data, figures, or other relevant material adequately describing the nature, cost, usage or other features of competing products."

[redacted] Indeed, Respondents cite no case that requires plaintiffs to conduct a "quantitative SSNIP" test or otherwise to analyze price changes or survey data. Resp. Post-Tr. Br. at 65. To the contrary, "Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one. This is because [t]he market, as most concepts in law or economics cannot be measured by metes and bounds." *Anthem*, 236 F. Supp. 3d at 193 (internal citations omitted). Contrary to Respondents' assertions, an economic expert's opinion does not need to be based on quantitative information to be probative. *See, e.g.*, *Phila. Nat'l Bank*, 374 U.S. at 362; *H & R Block*, 833 F. Supp. 2d at 88 (finding that an expert's opinion (even when limited by lack of data) can be helpful to corroborate other evidence in the record like "documents, testimony, and other evidence"); *Aetna*, 240 F. Supp. 3d at 47 (finding that Plaintiff's expert supported the predicted harm that "the merged firm would have the incentive and ability to increase [prices]"); *Sysco*, 113 F. Supp. 3d at 37. Moreover, requiring such a heightened standard would effectively create a safe harbor from antitrust enforcement for companies in industries where pricing data is unavailable in contravention of the plain language of the Clayton Act. 15 U.S.C. § 18. The Proposed Conclusion should be disregarded.

5. Complaint Counsel's Proposed Relevant Market Depends on Subjective and Changing Policy Assessments, Rather Than Established Law and Objective Evidence

49. Complaint Counsel seeks to dismiss the shortcomings in its proof by asserting that the relevant market is nascent and that there is limited economic evidence . (PFF ¶ 771.) It suggests that the law is specially written to protect nascent markets and that such markets are not inoculated from application of the antitrust laws. (PFF ¶ 771.)

Response to Proposed Conclusion No. 49

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is misleading and contrary to the law to the extent it implies that there can be no relevant market in, and thus antitrust laws do not apply to, innovative and developing markets. Instead, courts have consistently recognized that antitrust laws protect competition in developing, dynamic markets such as this one. *See, e.g.*, *Actavis*, 570 U.S. at 158 (recognizing that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" despite their being only the monopolist patent holder on the "market" to date); *Altitude Sports*, 2020 WL 8255520, at *13-14 (holding that plaintiffs' allegations of harm to a market that defendants had yet to participate in were sufficiently pleaded); *Ford Motor*, 405 U.S. 562 (analyzing the effect of a vertical merger on downstream barriers to entry); *Bazaarvoice*, 2014 WL 203966, at *70 (agreeing that firms who are entering the market may be considered "market participants and may be assigned market shares" for the purposes of antitrust analysis); *Town Sound & Custom Tops*, 959 F.2d at 480 (noting that courts have routinely defined antitrust markets that "include[] actual or potential competitors who may take business away from each other"); *SmithKline*, 575 F.2d at 1063. Moreover, Respondents

misstate Complaint Counsel's market definition. Complaint Counsel has defined the market for the research, development, and commercialization of MCED tests, not just an innovation market. Therefore, the Proposed Conclusion should be disregarded.

50. While it is true that Galleri is a nascent product, that other MCED tests in development do not even yet exist, and that that there is limited economic evidence, none of this relieves Complaint Counsel of its burden to prove the relevant market. The law does not set a different standard for establishing a nascent market. *See, e.g., Apartment Source*, 1999 WL 349938, at *1 (rejecting the plaintiffs' proposed market because "[a]n emerging submarket that has not yet developed into a distinct and identifiable market by definition is not well-defined, and therefore does not constitute a relevant product market under Section 2 of the Sherman Act."); *Epic Games, Inc. v. Apple Inc.*, No. 4:20–CV-05640–YGR, 2021 WL 4128925, at *56 (N.D. Cal. Sept. 10, 2021) (requiring all products in the mobile game apps market to be reasonably interchangeable and thus excluding certain gaming services from the product for being "too new" for the court to determine "whether consumes [*sic*] will or do consider these products reasonably interchangeable").

Response to Proposed Conclusion No. 50

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition.

The Proposed Conclusion is misleading and contrary to the law to the extent it implies that there can be no relevant market in, and thus antitrust laws do not apply to, innovative and developing markets. Instead, courts have consistently recognized that antitrust laws protect competition in developing, dynamic markets such as this one. *See, e.g.*, *Actavis*, 570 U.S. at 158 (recognizing that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" despite their being only the monopolist patent holder on the "market" to date); *Altitude Sports*, 2020 WL 8255520, at *13-14 (holding that plaintiffs' allegations of harm to a market that defendants had yet to participate in were sufficiently pleaded); *Ford Motor*, 405 U.S. 562 (analyzing the effect of a vertical merger on downstream barriers to entry); *Bazaarvoice*, 2014 WL 203966, at *70 (agreeing that firms who are entering the market may be considered "market participants and may be assigned market shares" for the

purposes of antitrust analysis); *Town Sound & Custom Tops*, 959 F.2d at 480 (noting that courts have routinely defined antitrust markets that "include[] actual or potential competitors who may take business away from each other"); *SmithKline*, 575 F.2d at 1063. Moreover, Respondents misstate Complaint Counsel's market definition. Complaint Counsel has defined the market for the research, development, and commercialization of MCED tests, not just an innovation market.

The Proposed Conclusion misinterprets the law. Respondents' citations to *Apartment Source* and *Epic Games* are inapposite. In the first instance, *Apartment Source* and *Epic Games* are cases brought under Section 2 of the Sherman Act. 1999 WL 349938 at *1. Congress intended Section 7 to have a lower standard than the Sherman Act for judging the legality of business combinations, and as such this case is inapposite. *Brown Shoe*, 370 U.S. at 318 ("Congress rejected, as inappropriate to the problem it sought to remedy, the application to § 7 cases of the standards for judging the legality of business combinations adopted by the courts in dealing with cases arising under the Sherman Act, and which may have been applied to some early cases arising under original § 7.") Further, the *Apartment Source* court did not hold that a relevant product market could not be defined in a dynamic market, but rather just that the argued submarket was not a distinct market given that plaintiffs did not show "any evidence that apartment communities within the Philadelphia Region recognize apartment locator services as a separate economic reality." 1999 WL 349938 at *24. Unlike the submarket in that case, here there is ample evidence that MCED test are a "separate economic reality" as shown by Complaint Counsel's application of the *Brown Shoe* practical indicia. Complaint Counsel's Post-Trial Brief § II.B.1. Therefore, the Proposed Conclusion should be disregarded.

51. Complaint Counsel's lax approach would not only relieve it of its burden of proof and substitute the agency's subjective and changing policy assessments for established law and objective evidence. No case supports the FTC's approach to market definition, which relies on platitudes about innovation instead of analysis grounded in the law and fact (CC Pretrial Br. At

2, 5 (noting that "Grail and its [alleged] competitors are engaged in an innovation race")). *See OrthoAccel Techs., Inc. v. Propel Orthodontics, LLC*, No. 4:16–CV-00350–ALM, 2017 WL 1213629, at *3 (E.D. Tex. Apr. 3, 2017) (requiring plaintiff to "plead a relevant product market in precise economic terms" despite it being "difficult to assess cross-elasticity of demand for nascent products in a relatively new market"); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.*, No. C-09–3854 MMC, 2010 WL 1541257, at *3 (N.D. Cal. Apr. 16, 2010), aff'd, 433 F. App'x 598 (9th Cir. 2011) (rejecting the plaintiffs' alleged product market because they failed to sufficiently allege interchangeability "both in the pharmaceutical product markets and in the innovation market for pharmaceutical products"). "Innovation is intangible, uncertain, unmeasurable, and often even unobservable, except in retrospect." Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 Antitrust L.J. 19, 27 (1995). Relying on truisms about innovation instead of rigorous analysis greatly increases the likelihood of false positives—a finding that a merger will substantially lessen competition in a relevant innovation market when, in fact, it would not. *See* Richard T. Rapp, Should Antitrust Enforcers Rely on Potential Competition Analysis or the Concept of Innovation Markets?, Written Testimony Before the Federal Trade Commission Hearings on Global and Innovation-Based Competition (Oct. 25, 1995). The potential harm from these false positives is especially great here where there is unrefuted evidence that the Transaction will save lives.

Response to Proposed Conclusion No. 51

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition.

The Proposed Conclusion is misleading and contrary to the law to the extent it implies that there can be no relevant market in, and thus antitrust laws do not apply to, innovative and developing markets for the reasons explained in Response to Proposed Conclusion No. 49, 50. Moreover, Respondents misstate Complaint Counsel's market definition. Complaint Counsel has defined the market for the research, development, and commercialization of MCED tests, not just an innovation market. The Proposed Conclusion is incorrect and misleading to the extent it implies that Complaint Counsel's market definition is not grounded in well-established, long-standing precedent supported by citations to a robust factual record. Complaint Counsel's Post-Trial Brief at 49-59; Complaint Counsel's Post-Trial Reply Brief § I.A.

The Proposed Conclusion is vague and misleading to the extent it implies that a market encompassing innovation will allow for too many false positives and, here, prevent this

Acquisition from saving lives. Respectfully, Respondents are wrong. Requiring a market to be mature before it comes within the reach of the antitrust laws removes a swath of competition from protection of the antitrust laws in contravention of the purpose of the Clayton Act. Here, it is not just Galleri that will save lives, but MCED tests collectively. And the best way to ensure that patients have their choice of high-quality, effective MCED tests is not by trusting Respondents but by trusting competition. As Dr. Cance from the American Cancer Society explained:

> Innovation in cancer detection, specifically multi-cancer early detection, is critical for driving improvements in cancer care and survival. To fuel innovation, it is extremely important to have multiple companies developing and continually improving this technology. ACS believes it is vital to enable different approaches to improving cancer detection. Having multiple approaches to compare against one another can ultimately lead to better clinical outcomes for patients and more cost-effective approaches to cancer detection for the benefit of patients. A good example of the importance of multiple approaches to innovation is the development and efficacy of COVID vaccinations from Pfizer, Moderna, Johnson & Johnson, AstraZeneca, Novavax, and others. At this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variations, RNA variations, protein markets, or some other method for detecting cancer in the blood will prove most effective.

(PX8398 (Cance (American Cancer Society) Decl. ¶ 11)).

For these reasons, the Proposed Conclusion should be disregarded.

52. Complaint Counsel's reliance on innovation principles to compensate for the infirmity of its case relies on a theory of harm that is not based on the ability of the merged entity to exercise market power but rather on the effects of the merger on abstract notions of competition. This approach is flawed, because, as a former Director of the Antitrust Division's Economic Policy Office explained: "[T]he research and development that is described as being of concern is not happening in a market . . . There are no arm's length transactions between suppliers and customers. There are no prices, there are no readily recognized indicia of market power. . . . [T]he concern has to be the consequences for output markets somewhere somehow." Federal Trade Commission Hearings on Global and Innovation-Based Competition (1995) (testimony of Lawrence White). Even if an innovation market approach were acceptable, Complaint Counsel cannot rely on it here because Dr. Scott Morton has not performed the necessary analysis. For an innovation market, the relevant definitional questions are: (i) "[D]id a hypothetical monopolist that controlled some set of assets to innovation . . . find it profitable to cut back on innovation?"; and (ii) to find the boundaries of the market, what are the firm's "capabilities to do innovation?" (PFF ¶ 772.) Dr. Scott Morton did no such analysis. (PFF

¶ 772 (RX6004 (Katz Trial Dep. at 26) ("I think it's clear that Professor Scott Morton when she applies her hypothetical monopolist test is applying it to defining a product market, not an innovation market.").)

Response to Proposed Conclusion No. 52

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition.

The Proposed Conclusion is incorrect, misleading, and contrary to the law to the extent it implies that Complaint Counsel's market definition is improper because Complaint Counsel relies on "innovation principles" for the reasons explained in Response to Proposed Conclusion No. 49, 50. The Proposed Conclusion is incorrect and misleading to the extent it implies that Complaint Counsel's market definition is not grounded in well-established, long-standing precedent supported by citations to a robust factual record. Complaint Counsel's Post-Trial Brief at 49-59; Complaint Counsel's Post-Trial Reply Brief § I.A. Respondents incorrectly assert that Dr. Scott Morton should have performed a different market definition analysis to properly define an innovation market. Respondents cite no case law but rely solely on the impermissible testimony of Dr. Katz in support of this contention. *See* (Response to RPFF ¶ 772). Moreover, Respondents misstate Complaint Counsel's market definition. Complaint Counsel has defined the market for the research, development, and commercialization of MCED tests, not just an innovation market. Therefore, the Proposed Conclusion should be disregarded

The Proposed Conclusion is contrary to modern economic theory to the extent it relies on policy statements and economics analysis from 1995. As modern economic theory recognizes—including Respondents own experts—innovation has competitive benefits that inure to consumers. (PX7132 (Willig (Illumina) Dep. at 117-18) (acknowledging the consumer benefits of R&D competition)); (PX7145 (Katz (Illumina) at 39) ("[I]nnovation and product variety, there are circumstances where both of those are beneficial to consumers, they are beneficial to the

economy overall, and so if they are stifled, in those circumstances, that would be in my view a bad thing.")).

B. Complaint Counsel Also Failed To Prove Its Alleged Related Product Market

53. In challenging a vertical merger, Complaint Counsel must demonstrate that "by altering the terms on which it provides a related product to one or more of its rivals, [the merged firm] would likely be able to cause those rivals to lose significant sales in the relevant market or otherwise compete less aggressively for customers." *Commentary on Vertical Merger Enforcement* (Dec. 2020) (withdrawn Sept. 2021) at 9. Defining a cognizable related product market is a necessary element of making this showing, since "[v]ertical restraints often pose no risk to competition unless the entity imposing them has market power, which cannot be evaluated unless the Court first defines the relevant market." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285, n.7 (2018); *see also Auburn News Co. v. Providence Journal Co*., 659 F.2d 273, 278 (1st Cir. 1981) ("Where substantial market power is absent at any one product or distribution level, vertical integration will not have an anticompetitive effect."); *Fruehauf Corp. v. FTC* 603 F.2d 345, 353 (2d Cir. 1979)..

Response to Proposed Conclusion No. 53

Complaint Counsel objects to the Proposed Conclusion because it misstates the law. The rule of reason framework is not applicable to merger challenges under Section 7 of the Clayton Act. *Brown Shoe*, 370 U.S. at 318 (rejecting the application of the heightened standard of the Sherman Act to Section 7 cases "as inappropriate to the problem it sought to remedy"). Congress passed the Clayton Act "to arrest restraints of trade in their incipiency and before they develop into full-fledged restrains violative of the Sherman Act." *Brown Shoe*, 370 U.S. at 323 n.39 (citing S. Rep. No. 81-1775, at 4298 (1950)). Congress expressly rejected the application of the heightened standard of the Sherman Act to Section 7 cases "as inappropriate to the problem it sought to remedy." *Brown Shoe*, 370 U.S. at 318. Rather "the legislative history of § 7 indicates clearly that the tests for measuring the legality of any particular economic arrangement under the Clayton Act are to be less stringent than those used in applying the Sherman Act." *Brown Shoe*, 370 U.S. at 328-29. The footnote from *American Express* that Respondents quote is appended to the proposition that "courts usually cannot properly apply the rule of reason without an accurate

definition of the relevant market." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018). This case is plainly inapposite because this is a merger challenge under Section 7 of the Clayton Act and the rule of reason framework does not apply in such cases. Likewise, *Auburn News* is a Sherman Act case that uses the rule of reason framework. *Auburn News Co. v. Providence J. Co.*, 659 F.2d 273, 275–76 (1st Cir. 1981) (explaining that case alleged violations of Sections 1 and 2 of the Sherman Act). Finally, the section of *Fruehauf* that Respondents cite says nothing remotely related to the need to define a related product market or the risk to competition from vertical restraints. *Fruehauf Corp. v. FTC* 603 F.2d 345, 353 (2d Cir. 1979) (stating nothing related to the need to define a related product market or the risk to competition from vertical restraints).

Respondents further misstate the law by claiming that the excerpt from *American Express* requires that a relevant market must be defined in markets where an anticompetitive effect is **not** alleged. Rather, the passage that Respondents cite clearly refers to defining the market where an anticompetitive effect **is** alleged. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018). For the reasons stated above, the Proposed Conclusion should be disregarded.

54. The requirement to prove a related product market can also be inferred from prior decisions on vertical mergers, even though courts may not have expressly considered the question. *Fruehauf Corp. v. FTC* concerned a government challenge of the merger between Fruehauf, the nation's largest manufacturer of truck trailers, and Kelsey, a manufacturer of various components to truck trailers, including heavy duty wheels ("HDWs") and antiskid braking devices ("ASBDs"). 603 F.2d 345, 347 (2d Cir. 1979). The FTC alleged that the acquisition would harm competition in the truck trailer market by enabling Kelsey to divert to Fruehauf HDWs that would otherwise go to Fruehauf's competitors. *Id.* at 354. The court rejected this contention, as it was based on the assumption that "Kelsey is a significant and substantial supplier of HDWs to Fruehauf's competitors", which had "no appreciable evidentiary support." *Id.* Critically, the *Fruehauf* court held that in assessing the anticompetitive effect of a vertical merger, it must measure "the degree of market power that would be possessed by the merged enterprise and *the number and strength of competing suppliers and purchasers*". *Id.* at 353 (emphasis added). Defining the relevant markets at all levels of the distribution chain is necessary to conduct such an analysis and the *Fruehauf* court did so: it defined the truck trailer

market, the HDW market and the ASBD market, with reference to total sales volume and Fruehauf's and Kelsey's respective market shares in each one. *Id.* at 349–51.

Response to Proposed Conclusion No. 54

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and mischaracterizes the case. *Fruehauf* concerned the acquisition of a manufacturer of heavy duty wheels ("HDWs") and antiskid braking devices ("ASBDs") by a manufacturer of truck trailers. *Fruehauf Corp. v. FTC* 603 F.2d 345, 348 (2d Cir. 1979). The FTC challenged the merger, alleging that it would substantially lessen competition in three markets: truck trailers, ASBDs, and HDWs. *Fruehauf*, 603 F.2d at 348. Respondents deceptively frame the case as alleging only harm in the market for truck trailers and argue that because the court also defined an HDW market and an ASBD market that related product market definitions were required. Rather, the HDW markets and ASBD markets in *Fruehauf* were actually *relevant* product markets in which the FTC alleged competitive harm, not related product markets as Respondents claim. 603 F.2d at 348-50. For the reasons stated above, the Proposed Conclusion should be disregarded.

55. Further, commentary on the Vertical Merger Guidelines supports the necessity of defining a related product market, especially in input foreclosure cases such as this one. In such cases, "it will be necessary to understand what inputs are included in the 'related product' category when there is actual input substitution." Jonathan B. Baker, Nancy L. Rose, Steven C. Salop & Fiona Scott Morton, *Recommendations and Comments on the Draft Vertical Merger Guidelines* (Feb. 24, 2020) at 6–7. In addition, it is necessary to understand (i) "whether price increases by the merging firm that produces the 'related product' will lead to accommodating price increases by its competitors that could exacerbate the anticompetitive potential of a price increase by the upstream merging firm" and (ii) "measure the share of output accounted for by the related product." *Id.*

Response to Proposed Conclusion No. 55

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it

should be disregarded. Moreover, the Proposed Conclusion misrepresents this commentary on the former Vertical Merger Guidelines, which explicitly *rejects* this requirement:

> The input is denoted a "related product" for which a formal market definition is not required. We agree that it may not be necessary to formally define a "related product" market for the purpose of enforcing Section 7 of the Clayton Act. That requirement could make the analysis more complex without improving the economic analysis.

Jonathan B. Baker, Nancy L. Rose, Steven C. Salop & Fiona Scott Morton, *Recommendations and Comments on the Draft Vertical Merger Guidelines* (Feb. 24, 2020) at 6.

[redacted] Respondents' own expert, Dr. Willig, agrees that it is unnecessary to go through a full market definition exercise for the related product; but rather it is sufficient to conduct a competitive analysis of the marketplace for the related product. (PX7132 (Willig Trial Dep. at 71-72)).

56. In its pre-trial brief, Complaint Counsel cited both *Brown Shoe* and *du Pont* to support its theory that it does not bear the burden to show a related product market. (CC Pretrial Br. at 49 (citing *Brown Shoe*, 370 U.S. at 325; *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593–95 (1957).) The burden to prove a related product market was not at issue in either case, and therefore cannot be fairly read to support Complaint Counsel's desired conclusion. In *Brown Shoe*, the Supreme Court held that the "relevant line[s] of commerce" were the markets for men's, women's and children's shoes, rather than the narrower proposed markets that Brown Shoe suggested. 370 U.S. at 326 (noting that Brown argued the district court's market definitions "fail to recognize sufficiently 'price/quality' and 'age/sex' distinctions in shoes"). While the Court did not consider the issue of a plaintiff's burden to define both a related and relevant product market, it explicitly discussed both Brown Shoe's and Kinney's market power in the *manufacture* and *retail* of men's, women's and children's shoes, respectively, as it related to the vertical harm that would arise from the merger. Brown was the fourth largest manufacturer and Kinney owned the largest chain of retail stores in the country. *Id.* at 332–33. Because of Kinney's market power in the related market, Brown would use its ownership of Kinney to force Brown shoes into Kinney stores, thereby foreclosing Brown's manufacturer competitors from access to Kinney's retail channel. *Id.* at 333. Kinney's market power in the related retail stores market was critical to such a finding.

Response to Proposed Conclusion No. 56

Complaint Counsel objects to the Proposed Conclusion because it is misleading, confusing, and mischaracterizes the cases. No court has ever required a plaintiff to define a "related product market" in a Section 7 challenge to a vertical merger. To the contrary, two Supreme Court decisions have held that vertical mergers violated Section 7 without requiring the definition of a related product market. *Brown Shoe*, 370 U.S. at 325-26, 334 (finding a Section 7 violation without requiring a showing that a related product constituted a relevant antitrust market); *du Pont*, 353 U.S. at 593-95 (same); *see also United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 195-97, 226-27 (D.D.C. 2018) (scrutinizing the "measure of customer loss" underpinning the Government's "increased-leverage theory" without requiring proof of the upstream firm's "'market power' in the programming market"). For the reasons stated above, the Proposed Conclusion should be disregarded.

57. Complaint Counsel also cites to the (now withdrawn) Vertical Merger Guidelines to support its claim that it need not define a related product market. However, nowhere did the Guidelines suggest that defining a related product market is unnecessary. In order to assess "the merged firm's rivals' ability to switch to alternatives to the related product", the Guidelines suggested reviewing "the types of evidence the Agencies use to evaluate customer switching when implementing the hypothetical monopolist test." Vertical Merger Guidelines § 4(a)). Invoking a hallmark principle of market definition to assess alternatives to the related product is inconsistent with a claim that the Guidelines did not require defining a related product market.

Response to Proposed Conclusion No. 57

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

58. In concluding that Illumina's NGS instruments and consumables comprise the related product market, Complaint Counsel did not conduct any detailed examination of "market data, figures or other relevant material adequately describing the nature, cost, usage or other features of competing products." *Grason Elec. Co.*, 571 F. Supp. at 1521 (citation omitted). Complaint Counsel did not undertake any effort to conduct a SSNIP test to determine whether the boundaries of the related product market were limited to Illumina's NGS systems, other NGS

systems, or non-NGS systems. *See Sysco*, 113 F. Supp. 3d at 33. Rather, it simply asserted that the related product market consisted of Illumina's NGS instruments and consumables, and nothing else.

Response to Proposed Conclusion No. 58

Complaint Counsel objects to the Proposed Conclusion because it is misleading, mischaracterizes the factual record, and misstates the law. No court has ever required a plaintiff to define a "related product market" in a Section 7 challenge to a vertical merger. To the contrary, two Supreme Court decisions have held that vertical mergers violated Section 7 without requiring the definition of a related product market. *Brown Shoe*, 370 U.S. at 325-26, 334 (finding a Section 7 violation without requiring a showing that a related product constituted a relevant antitrust market); *du Pont*, 353 U.S. at 593-95 (same); *see also United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 195-97, 226-27 (D.D.C. 2018) (scrutinizing the "measure of customer loss" underpinning the Government's "increased-leverage theory" without requiring proof of the upstream firm's "'market power' in the programming market"). Moreover, the extensive record evidence, as detailed in Complaint Counsel's briefings, thoroughly outlines the "nature, cost, usage, and other features" of NGS platforms and, specifically, MCED test developers' NGS platform requirements. Complaint Counsel's Post-Trial Brief at 67-77; (CCFF ¶¶ 925-1018). Through the record, Complaint Counsel has shown that Illumina's NGS platforms are a critical input to MCED tests, and there are no viable alternatives. Complaint Counsel's Post-Trial Brief at 67-79; (CCFF ¶¶ 1053-1211). Respondents support the Proposed Conclusion by inexplicably citing *Grason Electric*—a monopolization case in which the plaintiff asked the court to take judicial notice of the relevant product market. *Grason Electric Co. v. Sacramento Mun. Util. Dist.*, 571 F. Supp. 1504, 1521 (E.D. Cal. 1983). For the reasons stated above, the Proposed Conclusion should be disregarded.

59. Complaint Counsel's failure to properly define a related product market is fatal to its case, as proof of a related product market is an element of Complaint Counsel's case on which it bears the burden of proof. *See Arch Coal, Inc.*, 329 F. Supp. 2d at 116. As discussed *infra*, because the dynamics in the upstream market are critical to Complaint Counsel's theory of harm of foreclosure and raising rivals' costs, without properly defining the related product market, it cannot show that the merger is likely to "substantially lessen competition in the manner it predicts." *AT&T I*, 310 F. Supp. 3d at 194.

Response to Proposed Conclusion No. 59

Complaint Counsel objects to the Proposed Conclusion because it misstates the law, misrepresents the cases cited, and is misleading. *Arch Coal* is a wholly inapposite horizontal merger case that does not reference, in any conceivable way, a related product or related product market. *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109 (D.D.C. 2004). Respondents misleadingly insinuate that a passage of *AT&T* that discusses the plaintiff's burden to define "relevant product market(s)" also encompasses a novel requirement to define a related product market. 310 F. Supp. 3d at 194. The *AT&T* excerpt makes no mention of a related product market, and indeed, the *AT&T* court did not itself require a related product market element. *AT&T*, 310 F. Supp. 3d at 193; *see also United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 195-97, 226-27 (D.D.C. 2018) (scrutinizing the "measure of customer loss" underpinning the Government's "increased-leverage theory" without requiring proof of the upstream firm's "'market power' in the programming market"). No court has ever required a plaintiff to define a "related product market" in a Section 7 challenge to a vertical merger. To the contrary, two Supreme Court decisions have held that vertical mergers violated Section 7 without requiring the definition of a related product market. *Brown Shoe*, 370 U.S. at 325-26, 334 (finding a Section 7 violation without requiring a showing that a related product constituted a relevant antitrust market); *du Pont*, 353 U.S. at 593-95 (same). For these reasons, the Proposed Conclusion should be disregarded.

III. COMPLAINT COUNSEL FAILED TO PROVE THE TRANSACTION IS LIKELY TO SUBSTANTIALLY LESSEN COMPETITION

60. Complaint Counsel's failure to prove its relevant and related product market allegations is not the only reason its challenge to the Transaction is untenable. Assuming, *arguendo*, the relevant and related markets were as Complaint Counsel imagines, its case lacks merit because it is based on impermissible speculation. *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004) ("[A]ntitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future."). Such speculation cannot be the basis for the claim that the Transaction is likely to substantially lessen competition, as is required to establish a claim under Section 7 of the Clayton Act. *AT&T I*, 310 F. Supp. 3d at 194 (to prove a violation of the Clayton Act, the Government must show that "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger, "at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts.").

Response to Proposed Conclusion No. 60

The Proposed Conclusion should be disregarded to the extent it purports to provide factual conclusions about whether Complaint Counsel met burdens of proof. The Proposed Conclusion misstates Complaint Counsel's legal burden to prove a related product market, for which it provides no legal support. *See* Responses to Proposed Conclusions No. 53-55.

The Proposed Conclusion offers no new support or legal conclusion. It is duplicative of other proposed conclusions of law. *See* Responses to Proposed Conclusion No. 4-5. Like those proposed conclusions, this Proposed Conclusion is misleading and incomplete.

Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or in any activity affecting commerce in any section of the country[.]" 15 U.S.C. § 18. "Congress used the words '*may be* substantially to lessen competition' [] to indicate that its concern was with probabilities, not certainties[.]" *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 337 (3d Cir. 2016) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962) (emphasis in original); *see also In re Tronox Ltd.*, Docket No. 9377, 2018 WL 6630200, at *6 (F.T.C. Dec. 14, 2018) ("[I]t is not necessary to demonstrate certainty that a proposed merger will produce anticompetitive

effects, or even that such effects are highly probable, but only that the loss of competition is a sufficiently probable and imminent result of the merger or acquisition.") (quotations and citations omitted). Consequently, the Proposed Conclusion should be disregarded.

The Proposed Conclusion mischaracterizes the *AT&T* district court opinion, which in context states that the procompetitive benefits were conceded and therefore not implicated by any burden shifting. The full quote states, "The case at hand therefore turns on whether, notwithstanding the proposed merger's *conceded* procompetitive effects, the Government has met its burden of proof of establishing, through case-specific evidence, that the merger of AT&T and Time Warner, at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts." *AT&T*, 310 F. Supp. 3d at 194 (D.D.C.) (citations and quotations omitted) (emphasis added). For these reasons the Proposed Conclusion should be disregarded.

61. Complaint Counsel's challenge to this vertical merger cannot rely on any presumptions of harm that may be available in a horizontal case. As the Court of Appeals in *AT&T II* recognized, "unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share." *AT&T II*, 916 F.3d at 1032. Further much more is required than "testimony from third-party competitors" that is "speculative, based on unproven assumptions, or unsupported." *Id.* at 1038 (quoting *AT&T I*, 310 F. Supp. at 214). Rather, Complaint Counsel was required to bring forward substantial evidence that the Transaction likely will result in competitive harm that outweighs the Transaction's procompetitive benefits. As discussed below, Complaint Counsel failed to carry its burden of proving likely competitive harm by a wide margin.

Response to Proposed Conclusion No. 61

The Proposed Conclusion is misleading and incomplete. As one of Respondents' heavily cited cases states, there is a *per se* rule that potential foreclosure "amount[s] to a violation of § 7" when "the share of the market foreclosed reaches monopoly proportions." *Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir.1979) (citations omitted); *see also Brown Shoe,* 370 U.S. at 328-29 (noting that "the Clayton Act will, of course, have been violated" where "the share of the

market foreclosed is so large that it approaches monopoly proportions").

The cited portion of the *AT&T* district court opinion does not expound on any legal standard or proposition. It is merely a factual assessment of the strength and weaknesses of the categories of evidence presented at trial. In *AT&T*, the district court found that the Government provided "relatively weak documentary and third-party testimonial evidence" that was ultimately undermined by defendants. *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 219 (D.D.C. 2018). Here, however, Respondents fail to explain how the detailed and consistent third-party testimony in this case is unsupported, when in fact it is corroborated by ordinary-course documents, economics, and other evidence. *See* (CCFF ¶¶ 886-1901, 2607-4164). The deficiencies in *AT&T* are not present here, where robust documentary and testimonial evidence makes clear that Illumina has many ways to impact MCED test developers' ability to innovate and compete with Grail. (CCFF ¶¶ 2608-3078). For these reasons, the Proposed Conclusion should be disregarded.

62. More specifically, Complaint Counsel's case falls short because it (1) is based on assumptions unsupported by a reliable economic model and out of step with economic reality; (2) fails to account for the fact that foreclosing GRAIL's rivals would hurt Illumina's NGS sales and reputation; (3) disregards the fact that NGS costs will be a very small part of MCED test revenues and margins going forward; (4) offers no basis to predict any material diversion to Galleri from the alleged foreclosure strategy; (5) overlooks viable alternatives to Illumina's NGS products for MCED development; (6) misunderstands Illumina's prior vertical integrations and (7) ignores the Open Offer (see Section IV *infra*).

Response to Proposed Conclusion No. 62

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded. Moreover, the factual assertions within the Proposed Conclusion are incorrect. *See* Complaint Counsel's Post-Trial Reply Brief § III.

63. While the burden shifting framework announced in *U.S. v. Baker Hughes Inc.*, 908 F.2d 981, 990 (D.C. Cir. 1990) may apply, it operates differently for vertical mergers than it does for horizontal mergers. In particular, a challenge to a vertical merger must be assessed in the light of the widespread recognition that, unlike horizontal mergers, "most vertical mergers are procompetitive." 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law § 10A-1 (5th ed. 2021); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve.").

Response to Proposed Conclusion No. 63

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Nothing in the Proposed Conclusion contains legal support for the proposition that the *Baker Hughes* burden-shifting framework should apply differently for vertical cases, as the only cited caselaw is a Sherman Act conspiracy case. *See* Response to Proposed Conclusion No. 7 (detailing why the discussion of "horizontal agreements" compared to "vertical agreements" from *Republic Tobacco* is misleading and irrelevant).

The Proposed Conclusion is misleading and incomplete. Respondents agree that the *Baker Hughes* burden-shifting framework applies to this case. Resp. Pre-Tr. Br. at 43. According to that framework, Complaint Counsel makes a *prima facie* case that the Acquisition poses a reasonable probability of competitive harm, then the burden shifts to Respondents to present evidence for rebuttal. *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990). If Respondents successfully rebut the *prima facie* case, the burden shifts back to Complaint Counsel and merges with the ultimate burden of persuasion, which remains with Complaint Counsel at all times. *Baker Hughes*, 908 F.2d at 983.

Despite endorsing *Baker Hughes*, Respondents have asked this Court to burden

Complaint Counsel's *prima facie* case with all issues that courts ordinarily consider to be affirmative defenses under *Baker Hughes* and its progeny, such as entry, efficiencies, and remedy. Resp. Post-Tr. Br. at 130-31 (claiming that, in contrast to horizontal cases, here Complaint Counsel must prove a negative by showing that upstream entry will not constrain Illumina's ability and incentive to harm rivals as part of its *prima facie* case); Resp. Post-Tr. Br. 88-89 (criticizing Complaint Counsel's treatment of EDM and other efficiencies that are "relevant to whether Complaint Counsel can establish its *prima facie* case"); Resp. Post-Tr. Br. at 95 (arguing Complaint Counsel must account for the Open Offer as part of its *prima facie* case).

Respondents cherry-picked, out-of-context statement from Areeda & Hovenkamp is not representative of an economic consensus and does not justify creating novel legal standards. In fact, Respondents' own cited economic literature disagrees with their claim that vertical mergers are generally procompetitive. Jonathan B. Baker, Nancy L. Rose, Steven C. Salop & Fiona Scott Morton, *Recommendations and Comments on the Draft Vertical Merger Guidelines* (Feb. 24, 2020) at 2 ("The dVMGs do not make the old errors of saying that foreclosure is illusory, or that vertical mergers are typically procompetitive, irrespective of market structure. They properly decline to adopt an explicit procompetitive presumption. The agencies have made the correct decisions not to credit the erroneous claim that there is typically only a single monopoly profit . . . . These misguided ideas were properly excluded."); *id.* at 17 n.24 ("We have explained elsewhere why a procompetitive presumption is not in fact supported by economics literature, and we commend the agencies for declining to adopt it.") (citations omitted); Resp. Post-Tr. Br. at 74-75 (citing Jonathan Baker et al.); *see also* Gregory S. Crawford et al., *AT&T/Time Warner and Antitrust Policy Toward Vertical Mergers*, CPI, Antitrust Chron 3 n.5 (July 2019) (likening

the notion that vertical mergers are procompetitive based on few empirical studies to how opioids were initially considered to be non-addictive from a single paper that had "weak, weak, weak data;" "[w]e feel that a more nuanced and cautious view is warranted: if it was inexorable that integration enhances efficiency, the Soviet Union would have been the most efficient economy ever"); Resp. Post-Trial Br. at 91 n.13 (citing Crawford et al.). For these reasons, the Proposed Conclusion should be disregarded.

64. Complaint Counsel thus bears the burden to demonstrate that a vertical merger is anticompetitive when any resulting harm is balanced against any resulting efficiencies. The District Court of the District of Columbia applied this approach in *AT&T I*, the only vertical merger challenged by the DOJ in over four decades. 310 F. Supp. 3d 161. In rejecting the DOJ's challenge to the vertical merger at issue, the court in *AT&T I* observed that there is "recognition among academics, courts, and antitrust enforcement authorities alike that many vertical mergers create vertical integration efficiencies between purchasers and sellers." *Id.* at 193. The court described the government's burden under the *Baker Hughes* framework, explaining: "I will discuss the conceded consumer benefits associated with the proposed merger. Mindful of those conceded benefits, and the need to balance them against the Government's allegations of consumer harm, I will then evaluate whether the Government has carried its burden to show a likelihood that the challenged merger will result in a substantial lessening of competition." *Id*. at 195.

Response to Proposed Conclusion No. 64

The Proposed Conclusion is unsupported because none of the legal citations support a requirement that the Government bears the burden of demonstrating "any resulting harm is balanced against any resulting efficiencies." Accordingly, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

The Proposed Conclusion advocates for a novel burden that does not resemble the *Baker Hughes* framework, which Respondents agree applies here. *See* Response to Proposed Conclusion No. 63. But the Proposed Conclusion is misleading and incomplete. The Proposed Conclusion mischaracterizes the *AT&T* district court opinion's view of *Baker Hughes*, cherry-picking a quotation from the opinion meant to provide a roadmap for a section of the opinion,

misleadingly suggesting that the quote "described the government's burden under the *Baker Hughes* framework." Resp. Post-Tr. Br. at 88. The correct interpretation of the quote is clear with the proper context at the beginning of the paragraph: "*In the remainder of this section, I will analyze each of [the Government's] theories of harm to competition.* Initially, I will set forth the relevant market definition, which incorporates the Government's proposed product and geographic market. Next, I will discuss the conceded consumer benefits associated with the proposed merger. Mindful of those conceded benefits, and the need to balance them against the Government's allegations of consumer harm, I will then evaluate whether the Government has carried its burden to show a likelihood that the challenged merger will result in a substantial lessening of competition." *AT&T*, 310 F. Supp. 3d at 195 (D.D.C.) (emphasis added). The district court explained that *it*—not the Government—would ultimately balance the alleged harm with the conceded benefits; it did not say the Government itself needed to perform any balancing. When the district court explicitly addressed *Baker Hughes*, however, it stated, "Defendants assert that the burden-shifting framework is inapplicable to vertical merger cases, where no market-concentration-based presumption of harm attaches. As such, defendants argue that the Government has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case. I am skeptical of this position, both as a matter of law and logic." *Id.* at 191 n.17.

In effect, Respondents ask this court to create a novel burden that does not resemble *Baker Hughes* at all: the Government would need to prove anticompetitive effects, while simultaneously balancing harm against defendants' unsubstantiated alleged benefits and parrying all rebuttal arguments, all as part of its *prima facie* case. Resp. Post-Trial Br. 89. Such a burden is unparalleled in other Clayton Act cases—including vertical merger precedent—and even

exceeds the *prima facie* burden in Sherman Act cases. Even in Sherman Act cases—which involve stricter burdens for showing illegality than Clayton Act cases, *Brown Shoe*, 370 U.S. at 328-29—it remains defendants' burden to prove procompetitive justifications after the Government meets its *prima facie* burden. *Microsoft*, 253 F.3d at 59. Here, in contrast, Respondents argue Complaint Counsel must disprove or balance against their unsubstantiated efficiencies—in other words, their unsubstantiated procompetitive justifications for the Acquisition—as part of a *prima facie* case. *See, e.g.*, Resp. Post-Tr. Br. 88-89.

Respondents' approach is hostile to the very nature of the Celler-Kefauver Anti-Merger Act of 1950, which extended the Clayton Act to vertical mergers and clarified the lower standards for showing vertical merger illegality than under the Sherman Act. *Brown Shoe*, 370 U.S. at 317-19, 328-29 ("[T]he legislative history of § 7 indicates clearly that the tests for measuring the legality of any particular economic arrangement under the Clayton Act are to be less stringent than those used in applying the Sherman Act."). It is unclear what burden of production is left to shift to Respondents at all after the Government's *prima facie* case under their interpretation of the *Baker Hughes* framework; it collapses the entire framework into the initial step. *See* Complaint Counsel's Post-Trial Reply Brief § III.A. For these reasons, the Proposed Conclusion should be disregarded.

A. Complaint Counsel Offered No Reliable Model

65. To meet its burden here, Complaint Counsel was required to present a model showing any anticompetitive effects of the Transaction outweighed its efficiencies. *See, e.g., AT&T I*, 310 F. Supp. 3d at 237 (rejecting the government's challenge to the vertical merger for failure to meet "the Government's burden to adequately support its proffered [vertical theory of] harm"); *Fruehauf Corp.*, 603 F.2d at 355, 360 (rejecting the government's challenge to a vertical merger because its theories were based on "speculation rather than fact" with respect to one market and "too ephemeral" with respect to another market to prove that some degree of foreclosure would be sufficient to "significantly lessen" competition); *United States v. Hammermill Paper Co.*, 429 F. Supp. 1271, 1293–94 (W.D. Pa. 1977) (finding that "the United States has not carried its burden of proof that the effect of the [vertical] acquisition . . . may be substantially to lessen competition in the manufacture and sale of printing and fine paper in the

United States" because "the possibility of foreclosure of access by manufacturers is barred by" a multitude of factors).

Response to Proposed Conclusion No. 65

The Proposed Conclusion is unsupported because the cited cases do not support the proposition that "Complaint Counsel was required to present a model showing any anticompetitive effects of the Transaction outweighed the efficiencies." Accordingly, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

In their briefing, describe the "model" that they claim Complaint Counsel was required to present: "a complete [economic] model . . . to balance all the various economic factors that arise in an industry, including efficiencies, profit margins at both stages of production, reputational and contractual constraints on the merged firm, demand curves, substitution patterns, diversion ratios and upstream competition," that simultaneously accounts for the "timing and magnitude of potential harm versus likely benefit" resulting from the Acquisition. Resp. Post-Tr. Br. at 90-91. That is not the law, evinced by the fact that none of Respondents' legal citations supports this new burden.

Respondents' citation to *AT&T* for the claim that Complaint Counsel is "required to present a model," balancing anticompetitive effects with efficiencies is misleading for two reasons: (1) when read in its proper context, Respondents' cited portion of the *AT&T* district court opinion clearly does not opine on an economic model requirement; and (2) the *AT&T* D.C. Circuit opinion explicitly rejected such a requirement. First, the cited portion of the district court opinion in *AT&T* does not outline any relevant legal requirement—it stands only for the uncontroversial proposition that, when the Government opts to proffer an economic model to predict consumer harm, the Government must provide evidence to support that model. The cited

portion describes the inadequacies with the Government's economic expert's assumed degree of subscriber cord cutting as an input into his economic model. 310 F. Supp. 3d at 236-37 (D.D.C.). Whereas Respondents misleadingly excerpt from the cited portion to suggest the Government did not meet its "burden to adequately support its proffered [vertical theory of] harm" with an economic model, Resp. Post-Tr. Br. at 90, the district court's full quote states: "In the final analysis, it is the Government's burden to adequately support its proffered [economic] model's harm—and, necessarily, the model's inputs—through the testimony of its expert or related evidence." *AT&T*, 310 F. Supp. 3d at 237 (D.D.C.). The court concluded that, because the Government failed to support the assumed input in its economic model, it also "failed to provide adequate support for [its expert's other calculations that were dependent on that assumed input] and thus the model's predicted net consumer harm." *Id.* The need to support assumed inputs to a proffered economic model with evidence does not mean the Government must present an economic model in every *prima facie* case.

Second, the D.C. Circuit opinion affirming *AT&T* explicitly rejected Respondents' claimed standard as contrary to Supreme Court precedent. In evaluating whether the lower court erred in its treatment of the Government's economic expert's model, the D.C. Circuit held that quantitative evidence is not required for a successful vertical merger challenge, citing the Supreme Court's ruling in *Ford Motor*. *AT&T*, 916 F.3d at 1045-46 (D.C. Cir.) (citing *Ford Motor*, 405 U.S. at 567-69, 578). Thus, the D.C. Circuit opinion—upon which Respondents rely heavily throughout their post-trial brief—explicitly rejected the burden Respondents seek to impose here. *See* Complaint Counsel's Post-Trial Reply Brief § III.A.2. For these reasons, the Proposed Conclusion should be disregarded.

66. As Respondents' economics expert Dr. Carlton explained, "vertical merger analysis requires a complete model . . . that you quantitatively can use to balance all the various

economic factors that arise in an industry", including efficiencies, profit margins at both stages of production, reputational and contractual constraints on the merged firm, demand curves, substitution patterns, diversion ratios and upstream competition. (PFF ¶¶ 802-03). Ultimately, if the model does not "take account of the efficiencies, or more broadly the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've failed to balance the benefits against the possible harms." (PFF ¶ 803.1.) The model must also take account of the "timing and magnitude of potential harm versus likely benefit" because "if the harms are far off in the future, but the benefits are closer in", that critical balance of potential harms versus benefits would be skewed and a procompetitive vertical merger could, as a result, be disallowed, depriving consumers of enormous benefits. (PFF ¶ 805.)

Response to Proposed Conclusion No. 66

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. It merely relies on the self-serving opinion of Respondents' paid economic expert, Dr. Dennis Carlton. It is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. The contents of the Proposed Conclusion are also incorrect. *See* Complaint Counsel's Post-Trial Reply Brief § III.A.2. Consequently, it should be disregarded.

67. As a leading antitrust treatise explains, "there is no comparable theoretical basis for dealing with vertical mergers" as with horizontal mergers. 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1000a (5th ed. 2021). "[W]hether vertical mergers are likely to harm competition, and under what circumstances, are ultimately empirical questions." Gregory S. Crawford, et al, *AT&T/Time Warner and Antitrust Policy Toward Vertical Mergers*, CPI Antitrust Chron, 2, 3 (July 2019).

Response to Proposed Conclusion No. 67

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. To the extent it suggests that there is a legal requirement to present an empirical model for a successful vertical merger challenge, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

The Proposed Conclusion is confusing and vague. It is unclear what is meant by "no comparable theoretical basis for dealing with vertical mergers" or what legal standard it

proposes. The Proposed Conclusion's reliance on the quote Gregory Crawford et al. is misleading. The article describes the need for more empirical work to determine whether vertical mergers are generally pro- or anticompetitive, not a legal requirement. Specifically, the article states, "[E]conomists developed rigorous anticompetitive theories of vertical integration. Most significantly, models emerged showing that an integrated firm may have an incentive to foreclose rivals' access to inputs or . . . raise their costs of these items. . . . These models answered the Chicago School challenge by showing that anticompetitive effects were a logical possibility. With rigorous models showing both pro- and anticompetitive effects, the question of whether vertical mergers are likely to cause harm, and in what circumstances, ultimately is an empirical one." Gregory S. Crawford et al., *AT&T/Time Warner and Antitrust Policy Toward Vertical Mergers*, CPI Antitrust Chron. at 2-3 (July 2019). The Proposed Conclusion's quoted section discusses empirical work on vertical mergers broadly rather than a legal requirement for a successful merger challenge. Not only does the source not support any legal requirement for an empirical model, it undercuts Respondents' claim that vertical mergers are generally procompetitive: "While one might think from the writings of some commentators that hundreds of studies have shown [consumer benefits from vertical mergers], this conclusion would be wrong." Crawford et al. at 3 (noting that "surprisingly little empirical work has documented [beneficial EDM] effects"). For these reasons, the Proposed Conclusion should be disregarded.

68. Complaint Counsel and its expert, Dr. Scott Morton, did not offer any quantitative model that balances all the economic factors that arise. (PFF ¶ 808.) Rather they simply assumed—contrary to the undisputed evidence—that there are no efficiencies and pinned their case on a thought exercise on what might happen under a series of unproven assumptions. That is not enough to stop a life-saving Transaction. The undisputed evidence showed that the Transaction will generate huge efficiencies, accelerating patient access to Galleri, at lower prices, resulting in thousands of lives saved with monetary benefits exceeding $35 billion. (PFF ¶ 1123.)

Response to Proposed Conclusion No. 68

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. The contents of the Proposed Conclusion are also incorrect. *See* Complaint Counsel's Post-Trial Reply Brief § III.A.2. Consequently, it should be disregarded.

69. At bottom, Dr. Scott Morton's "model" amounts to hand-waving; neither she nor Complaint Counsel conducted a serious analysis of the factors required to reliably model the effects of a vertical merger. (PFF ¶ 808–814.) Their failure to put forward a full model of the effects of the Transaction is fatal to Complaint Counsel's challenge of the Transaction.

Response to Proposed Conclusion No. 69

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. The contents of the Proposed Conclusion are also incorrect. *See* Complaint Counsel's Post-Trial Reply Brief § III.A.2. Consequently, it should be disregarded.

70. Furthermore, to demonstrate "the probable anticompetitive effect of the merger" Complaint Counsel must show that Illumina's likely incentives absent the transaction would be different, or else there could be no merger-specific "effect". *AT&T I*, 310 F. Supp. 3d at 190 (internal quotations omitted). In other words, Complaint Counsel must prove that the Transaction will change the *status quo* to a large enough extent to substantially lessen competition. Complaint Counsel's showing fails here as well.

Response to Proposed Conclusion No. 70

The Proposed Conclusion is unsupported for the proposition that Complaint Counsel "must show that Illumina's likely incentives absent the transaction would be different, or else there could be no merger-specific 'effect'" or that "Complaint Counsel must prove that the Transaction will change the *status quo* to a large enough extend to substantially lessen competition." The cited portion of *AT&T* does not discuss the requirement to show different incentives or that they must change to an undefined "large enough extent" to have some effect.

Accordingly, the Proposed Conclusion is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. The Proposed Conclusion also contains unsupported factual conclusions that are inappropriately included here. The legal and factual contents of the Proposed Conclusion are incorrect. *See* Complaint Counsel's Post-Trial Reply Brief § III.A. Consequently, the Proposed Conclusion should be disregarded.

71. By electing not to conduct a proper analysis of Illumina's incentives absent the merger, Complaint Counsel failed to prove a "probable anticompetitive *effect of the merger*". *AT&T I*, 310 F. Supp. 3d at 190 (emphasis added).

Response to Proposed Conclusion No. 71

The Proposed Conclusion is not a proposed conclusion of law. It is a factual conclusion. It does not expound on any legal standard or proposition. Moreover, the conclusion is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Respondents appear to have emphasized "effect of the merger" from *AT&T* to suggest Complaint Counsel was legally required to show changed incentives through a vague "proper analysis." But the quote is an out-of-context statement from a passage that did not discuss any incentives analysis. *AT&T*, 310 F. Supp. 3d at 190 (D.D.C.). Moreover, the remaining contents of the Proposed Conclusion are incorrect. *See* Complaint Counsel's Post-Trial Reply Brief § III.A. Consequently, it should be disregarded.

72. Complaint Counsel effectively asks the Court to adopt a presumption against vertical mergers, though "no body of empirical evidence" supports such a presumption (based on structure or any other grounds)", Kobayashi & Muris, at 2, and the law is clear that Complaint Counsel bears the burden to prove the Transaction unlawful, *AT&T I*, 310 F. Supp. 3d at 194; *FTC v. Rag-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020).

Response to Proposed Conclusion No. 72

The Proposed Conclusion is vague because it does not define "burden to prove the Transaction [sic] unlawful." Complaint Counsel has no specific response to the extent the

Propose Conclusion suggests the Government bears the ultimate burden of persuasion, *Baker Hughes*, 908 F.2d at 983. But for any other interpretation, as well as the remainder of the Proposed Conclusion, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

The Proposed Conclusion cites an ostensibly independent article that, in fact, Respondents themselves helped manufacture: Bruce Kobayashi and Timothy Muris' article about the merits of this case. Bruce H. Kobayashi and Timothy J. Muris, *Screening Out Innovation—Vertical Merger Principles and the FTC's Misapplication in the Illumina-GRAIL Case*, Competitive Enterprise Institute (2021) [hereinafter "Kobayashi & Muris"]). In their briefing, Respondents tout the authors as authorities on "the economic literature, existing legal framework, and history of government merger enforcement" who have written about what they "observed" about this litigation. Resp. Post-Tr. Br. at 96. Regardless of the authors' views about what the law is or should be, the article is not caselaw and is therefore irrelevant.

The contents of the Kobayashi & Muris article are, in no uncertain terms, merely Respondents' advocacy with a thin veneer of legitimacy. Illumina provided comments on the authors' drafts and the authors thanked Illumina for its contributions at the conclusion of the article. Kobayashi & Muris at 36 ("The authors thank the Competitive Enterprise Institute, Illumina, and John Yun for comments on earlier drafts."). While that alone is sufficient to question the objectivity and reliability of the article's contents, the inherent bias does not end there. [redacted]

[redacted] In fact, one author's law firm "lobbied on the Illumina-GRAIL merger," showing his explicit financial ties with Respondents and their success in this proceeding. Kobayashi & Muris at 36.

Respondents seek to circumvent this Court's judgment as to the admissibility of the opinions of the authors as amici curiae. Such a tactic is unsurprising considering the article clearly "serv[es] as a mere conduit for the views of one of the parties'" in direct contrast to this Court's instruction. *In the Matter of Illumina, Inc. and GRAIL, Inc.*, Order Denying Motion for Leave to File Amicus Curiae Brief, Docket No. 9401 (Nov. 5, 2021) (quoting Wright & Miller, Fed. Prac. & Proc. § 3975).

Essentially this article is commissioned expert testimony that Respondents attempt to admit into the record surreptitiously in direct contravention of the Scheduling Order in this case, the Part 3 Rules, and the Federal Rules of Evidence. Collectively, these rules provide a procedure for the admissions of expert testimony and are designed to allow the opposing side to probe the veracity of the expert opinion, both for admissibility as well as for probative value. Complaint Counsel was afforded none of these protections. Instead, Respondents quoted this out-of-record, self-orchestrated opinion testimony to get around this Court's prior rulings and to sidestep the procedures designed to ensure a fair trial. Moreover, the contents and

characterizations of Complaint Counsel's advocacy are incorrect. *See* Complaint Counsel's Post-Trial Reply Brief § III.A. Consequently, the Proposed Conclusion should be disregarded.

B. Complaint Counsel's Approach Is Out of Step With Economic Reality

73. Evaluating the effect of any merger requires consideration of the transaction's effect on the marketplace, which necessarily entails consideration of the economic reality. *See, e.g.*, *AT&T II*, 916 F.3d at 1038 (holding that "the government had not met its first-level burden of proof" as "[n]either the model nor Professor Shapiro's opinion accounted for the effect of the irrevocably-offered arbitration agreements, which the district court stated would have 'real world effects' on negotiations"); *FTC v. Libbey*, 211 F. Supp. 34, 46 (D.D.C. 2002) (criticizing the FTC for predicating its request for an injunction on the terms of an original merger agreement rather than the amended agreement). Yet here, neither Complaint Counsel nor its expert took account of the Open Offer in balancing the alleged harms of the Transaction against its demonstrated efficiencies. They simply dismissed the Open Offer as a conduct remedy that they view as insufficient by itself to alleviate their concerns about the Transaction.

Response to Proposed Conclusion No. 73

The Proposed Conclusion is misleading and incomplete. Clayton Act precedent is clear that courts only consider remedies *after* they analyze a merger's competitive effects and determine a violation has occurred, in which case it is the merging parties' burden to show their proposed remedy is adequate to ameliorate the harm caused by the violation. *See* Complaint Counsel's Post-Trial Brief § II.F.3. It would be hostile to Section 7 precedent to put the burden on Complaint Counsel, in making its *prima facie* case that a violation occurred, to disprove the efficacy of Respondents' proposed remedy in mitigating the violation.

The Proposed Conclusion's reliance on the D.C. Circuit opinion in *AT&T* to contradict this precedent is misplaced. As an initial matter, the district court's statements regarding defendants' arbitration agreements are dicta. The court determined that the defendants rebutted the Government's *prima facie* case without assessing their arbitration agreements. *AT&T*, 310 F. Supp. 3d at 241 (D.D.C.) (Having already concluded that the Government's increased leverage theory failed after considering rebuttal evidence, the court described the effects of arbitration agreements as "amount[ing] to extra icing on a cake already frosted.") (citations and quotations

omitted). Second, the D.C. Circuit also noted that the district court characterized the no-blackout agreements as "extra icing on a cake already frosted." *AT&T*, 916 F.3d at 1038, 1041 (D.C. Cir.). The strained reading of a district court's dicta is no substitute for a framework outlined in decades of clear Clayton Act precedent. Moreover, *AT&T* also involved a unique set of facts. The Government only alleged a price-based harm. *AT&T*, 310 F. Supp. 3d at 201 (D.D.C.). The unilateral theory of harm rested solely on the combined company's post-merger increased incentive to leverage programming content blackouts during supply negotiations with downstream competitors, not on a foreclosure theory like here. *AT&T*, 310 F. Supp. 3d at 201 (D.D.C.).

FTC v. Libbey is inapposite. *Libbey* involved the FTC's suit against a horizontal merger where the parties amended their merger agreement to include a structural remedy—a divestiture—and the court nevertheless granted the FTC an injunction against the merger. *FTC v. Libbey*, 211 F. Supp. 2d 34, 46, 51-52 (D.D.C. 2002). [redacted]

[redacted] Consequently, the Proposed Conclusion should be disregarded.

74. While Complaint Counsel and its expert erred in dismissing the Open Offer as a viable "remedy" (as is discussed in Section IV below), that is a different matter from its impact on the likely real-world effects of the merger as mandated by the Clayton Act. Complaint Counsel failed altogether to factor the Open Offer into the assessment of the merger's real-world effects, instead taking the position that the Open Offer can be analyzed merely as a remedy to a proven anticompetitive merger. However, the Open Offer is a binding contractual commitment, just as Illumina's customer supply agreements are binding commitments and, therefore, a real-world fact that impacts Illumina's incentives and constrains its conduct. As such, Complaint Counsel must account for the effects of the Open Offer, just as it is required to account for all relevant economic facts in its attempt to demonstrate foreclosure effects as part of its prima facie case. *See Arch Coal*, 329 F. Supp. 2d at 159 (citing defendants' post-merger transaction commitment in rejecting claim of harm). As the Court of Appeals in *AT&T II* observed, the government has previously recognized that, "especially in vertical mergers, conduct remedies . . . can be a very useful tool to address the competitive problems while preserving competition and allowing efficiencies that may result from the transaction." *AT&T II,* 916 F.3d at 1041 (internal quotations omitted). And where an irrevocable offer to customers guaranteeing fair treatment is

made by the merging firm, the government's speculative claims of changed incentives, without taking that offer into account, become "largely irrelevant". *See id.* at 1046–47 (noting that "the government failed to meet its burden of proof" because DOJ's expert had not considered the effect of offers of arbitration agreements). Thus, Complaint Counsel's challenge to the Transaction fails for yet another reason: it is divorced from economic realities and evidence.

Response to Proposed Conclusion No. 74

The Proposed Conclusion is misleading and incomplete. Respondents' behavioral remedy is in direct contrast to *Arch Coal*, where—despite Respondents' characterization of a "post-merger transaction commitment"—the merging parties entered into permanent divestiture agreements (*i.e.*, structural remedies) that changed market structure. In *Arch Coal*, the merging parties entered into a divestiture agreement to divest themselves of assets that the FTC previously deemed problematic. *Arch Coal*, 329 F. Supp. 2d at 114.

Clayton Act precedent is clear that courts only consider remedies *after* they analyze a merger's competitive effects and determine a violation has occurred, in which case it is the merging parties' burden to show their proposed remedy is adequate to ameliorate the harm caused by the violation. *See* Complaint Counsel's Post-Trial Brief § II.F.3. It would be hostile to Section 7 precedent to put the burden on Complaint Counsel, in making its *prima facie* case that a violation occurred, to disprove the efficacy of Respondents' proposed remedy in mitigating the violation.

The Proposed Conclusion's reliance on the D.C. Circuit opinion in *AT&T* to contradict this precedent is misplaced. As an initial matter, the district court's statements regarding defendants' arbitration agreements are dicta. The court determined that the defendants rebutted the Government's *prima facie* case without assessing their arbitration agreements. *AT&T*, 310 F. Supp. 3d at 241 (D.D.C.) (Having already concluded that the Government's increased leverage theory failed after considering rebuttal evidence, the court described the effects of arbitration agreements as "amount[ing] to extra icing on a cake already frosted.") (citations and quotations

omitted). Second, the D.C. Circuit also noted that the district court characterized the no-blackout agreements as "extra icing on a cake already frosted." *AT&T*, 916 F.3d at 1038, 1041 (D.C. Cir.). The strained reading of a district court's dicta is no substitute for a framework outlined in decades of clear Clayton Act precedent. Moreover, *AT&T* also involved a unique set of facts. The Government only alleged a price-based harm. *AT&T*, 310 F. Supp. 3d at 201 (D.D.C.). The unilateral theory of harm rested solely on the combined company's post-merger increased incentive to leverage programming content blackouts during supply negotiations with downstream competitors, not on a foreclosure theory like here. *AT&T*, 310 F. Supp. 3d at 201 (D.D.C.). [redacted] Consequently, the Proposed Conclusion should be disregarded.

C. Complaint Counsel's Foreclosure Theory Fails, Because There Is No Basis To Predict Any Material Diversion to Galleri from the Alleged Foreclosure Strategy

75. Having failed to prove that the MCED tests in development will be close substitutes to Galleri, Complaint Counsel failed to prove material diversion. *See HTI Health Servs*, 960 F. Supp. at 1136 (rejecting the plaintiff's diversion theory because the "testimony and expert opinion regarding a potential shift in patient admissions to ParkView is conjecture that is based on an assumption lacking in evidentiary support"); *Crouse-Hinds Co. v. InterNorth, Inc.*, 518 F. Supp. 416 (N.D.N.Y. 1980) (rejecting the plaintiff's foreclosure claim because of the "limited evidence adduced by the plaintiff . . . to even give a rough estimate of the degree of foreclosure" and "the statistics that . . . [did] not indicate a substantial foreclosure").

Response to Proposed Conclusion No. 75

The Proposed Conclusion is unsupported to the extent that it relies on the cited caselaw for the proposition that Complaint Counsel was required to "prove material diversion." It is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

Respondents argue that the Complaint Counsel did not prove any "diversion," which they

define as showing "divert[ed] sales to GRAIL from GRAIL's purported rivals," Respondent's Post-Tr. Br. at 97, and therefore Complaint Counsel did not meet its burden. [redacted]

However, caselaw does not require proof of diversion as part of the Government's *prima facie* case in a vertical merger challenge. Despite decades of successful vertical merger challenges, no court has required the Government to prove a certain degree of "divert[ed] sales to [the merged firm] from [downstream] rivals." Resp. Post-Tr. Br. at 97; *Brown Shoe* 370 U.S. 294; *Ford Motor*, 405 U.S. 562 (1972); *U.S. Steel*, 426 F.2d 592 (6th Cir. 1970); *Union Carbide*, 59 F.T.C. 614, 1961 WL 65409, (1961).

Rather than address long-standing precedent, Respondents contort a handful of district court opinions—none of which actually assess diversion or make it a prerequisite for a successful vertical merger challenge—to fit their argument. Respondents cite *HTI Health Servs. v. Quorum Health Grp., Inc.*, 960 F. Supp. 1104 (S.D. Miss. 1997), which Respondents say "reject[ed] the plaintiff's diversion theory" because of the limited evidence provided by plaintiffs. Resp. Post-Tr. Br. at 99-100. But the *HTI* court never said the plaintiff presented a "diversion theory," engaged in any sort of analysis like the "diversion" analysis Respondents claim is a prerequisite to showing harm, or opined on whether such a diversion analysis is necessary for a successful vertical merger challenge. *HTI* only discussed the potential harm of an upstream physicians' practice steering customers to an affiliated hospital downstream. What Respondents erroneously call "diversion" there was the potential foreclosure itself—steering patients to an affiliated hospital downstream—not the potential downstream diversion from the foreclosure. *HTI*, 960 F. Supp. at 1136-37 (citing *Fruehauf*, 603 F.2d at 354).

Similarly, *Crouse-Hinds Co. v. InterNorth, Inc.*, 518 F. Supp. 416 (N.D.N.Y. 1980)—Respondents' other cited case—also does not also does not involve the type of diversion Respondents discuss here. Resp. Post-Tr. Br. at 97. As such neither case is supportive of Respondents' proposition. [redacted] Consequently, the Proposed Conclusion should be disregarded.

76. Complaint Counsel and Dr. Scott Morton speculate that current differentiation does not matter because they say the tests in development can easily and swiftly jump from single- or few-cancer tests to 50-cancer tests. But attorney argument and an economist's speculation cannot outweigh the uncontested evidence to the contrary. *Arch Coal, Inc.*, 329 F. Supp. 2d at 117 ("[A]ntitrust theory and speculation cannot trump facts")

Response to Proposed Conclusion No. 76

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. It is a factual conclusion that cites an unrelated, generalized statement from a horizontal merger case that is duplicative of other Proposed Conclusions. *See* Response to Proposed Conclusion No. 5, 60. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. [redacted] Consequently, the Proposed Conclusion should be disregarded.

D. Complaint Counsel Failed to Account for the Impact Any Attempted Foreclosure would have on Illumina's NGS Sales and Reputation

77. Further undermining its case is the fact that Complaint Counsel's foreclosure theory does not account for the impact of an attempted foreclosure strategy on Illumina's upstream sales and reputation. *See, e.g.*, *AT&T I*, 310 F. Supp. 3d 161, 243–44 (2018) (rejecting the government's vertical foreclosure theory because "it would be 'profitable' for the merged entity to continue to license [upstream] Time Warner content to [downstream competitors] virtual MVPDs" and to "maximize distribution of Turner content"); *Fruehauf Corp. v. FTC*, 603 F.2d 345, 354 (2d Cir. 1979) (rejecting the Commission's assumptions of vertical foreclosure and diversion because upstream supplier, Kelsey, "would risk [customers'] retaliating by shifting

to competing suppliers not only their purchases of [Heavy Duty Wheels] HDWs but of other products presently bought from Kelsey, which could cause it greater economic harm"); *HTI Health Servs. Inc. v. Quorum Health Grp., Inc.*, 960 F. Supp. 1104, 1137 (S.D. Miss. 1997) (rejecting the plaintiff's vertical foreclosure theory because "any financial incentive or alleged ability on the part of the [upstream] Vicksburg Clinic physicians to shift patients to [downstream] ParkView is negated by" "a countervailing economic incentive . . . to maintain a cooperative association with [ParkView's competitors]").

Response to Proposed Conclusion No. 77

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. [redacted] Moreover, to the extent it proposes a legal standard that the Government must account for the "impact" or "upstream sales and reputation," it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is misleading and incomplete because the cited cases are inapposite. *AT&T* involved an upstream related product provider—Turner's programming business—that faced robust competitive pressures from tech firms such as Netflix, Hulu, and Amazon. 310 F. Supp. 3d at 175-76 ("It is therefore no surprise that programmers and distributors alike have noted the competitive threat posed by [on demand services]. After all, as Nobel laureate Bob Dylan correctly observed: 'You don't need a weatherman to know which way the wind blows.'"). Likewise, in *Fruehauf*, there was significant risk of losing business to the many upstream competitors. 603 F. 2d at 354 ("[T]he record reviews that [downstream firms] have in the past purchased almost all of their [upstream products] from other suppliers [than the upstream merging party]. . . . Thus [the upstream merging party], while a large manufacturer of [the related product], has hardly been a substantial supplier [of the relevant

market.]"). [redacted] This case is also different from *HTI*, where the upstream physicians did not want to steer patients to an affiliate hospital at the expense of the plaintiff because they had a "countervailing economic incentive" from the plaintiff who was leasing office space to them and they wanted to avoid eviction. *HTI*, 960 F. Supp. 1104, 1137 ("[T]he Court finds as fact that [the upstream physicians' practice's] current office lease arrangement with [the plaintiff] . . . creates a countervailing economic incentive for the physicians to maintain a cooperative association with [the plaintiff]. . . . Thus, in light of [the upstream physicians' practice's] need for office space [and their] concerns that [the plaintiff], as lessor, might exercise its eviction powers [and other medical treatment-related factors]" the court concluded the physicians would not steer patients to an affiliate hospital.) Suffice to say MCED test developers wield no such power over Illumina here. Accordingly, the Proposed Conclusion should be disregarded.

78. Complaint Counsel's foreclosure argument as to what might happen 10 or more years from now is mere conjecture, and "speculation cannot trump facts". *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116 (D.D.C. 2004).

Response to Proposed Conclusion No. 78

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. It is a factual conclusion that cites an unrelated, generalized statement from a horizontal merger case that is duplicative of other Proposed Conclusions. *See* Response to Proposed Conclusion No. 5, 60. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. [redacted] Consequently, the Proposed Conclusion should be

disregarded.

79. In view of the impact foreclosure would have on Illumina's sales and reputation, the only way Illumina could have an incentive to foreclose GRAIL's rivals—whether by attempting to cut off their supply of Illumina NGS products, rasising their costs, withholding services, or otherwise—is if foreclosure diverted enough sales from GRAIL's rivals to recoup all the losses resulting from the damage foreclosure would cause to Illumina's upstream sales and reputation. *See, e.g.*, *AT&T*, 310 F. Supp. 3d at 251; *HTI Health Servs.*, 960 F. Supp. 1136–37 (S.D. Miss. 1997); *Fruehauf*, 603 F.2d at 359.

Response to Proposed Conclusion No. 79

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. It is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. It is a factual conclusion about aspects of the evidence, which it misstates, and is duplicative of other Proposed Conclusions. For the reasons explained in Responses to Proposed Conclusions No. 75, 77, this Proposed Conclusion should likewise be disregarded.

80. Complaint Counsel failed altogether to show that the revenue and reputation losses that Illumina would incur by foreclosing GRAIL's rivals would be offset by any additional profits it would make from rival sales diverted to Galleri. Thus, Complaint Counsel failed to meet its burden, which cannot be satisfied with speculation. *AT&T*, 310 F. Supp. 3d at 251 (rejecting the government's vertical foreclosure theory because the government offered insufficient evidence to show "that HBO promotions [the upstream products] were so valuable that withholding or restricting them would drive customers to AT&T [the downstream firm]") (emphasis added); *HTI Health Servs., Inc.*, 960 F. Supp. at 1136 (finding no foreclosure because there was "no credible evidence that postmerger financial incentives [would] cause the Vicksburg Clinic physicians [upstream suppliers] to shift their hospital patient admissions to ParkView [downstream firm]" away from ParkView's competitors); *Fruehauf Corp.*, 603 F.2d at 359 (rejecting the FTC's vertical foreclosure theory in part because the Commission erroneously assumed that the "corporation being acquired [the upstream supplier of Heavy Duty Wheels and other products] . . . would divert to [the downstream] acquiring corporation sales that would otherwise be made to other customers").

Response to Proposed Conclusion No. 80

The Proposed Conclusion is not a conclusion of law. It is an erroneous factual conclusion—that "Complaint Counsel failed to show" certain facts and thus, according to Respondents, "failed to meet its burden." The Proposed Conclusion does not expound on any

legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is misleading and incomplete. The cited cases are inapposite. *AT&T* involved an upstream related product provider—Turner's programming business—that faced robust competitive pressures from tech firms such as Netflix, Hulu, and Amazon. 310 F. Supp. 3d at 175-76 ("It is therefore no surprise that programmers and distributors alike have noted the competitive threat posed by [on demand services]. After all, as Nobel laureate Bob Dylan correctly observed: 'You don't need a weatherman to know which way the wind blows.'"). Likewise, in *Fruehauf*, there was significant risk of losing business to the many upstream competitors. 603 F. 2d at 354 ("[T]he record reviews that [downstream firms] have in the past purchased almost all of their [upstream products] from other suppliers [than the upstream merging party]. . . . Thus [the upstream merging party], while a large manufacturer of [the related product], has hardly been a substantial supplier [of the relevant market.]"). [redacted] This case is also different from *HTI*, where the upstream physicians did not want to steer patients to an affiliate hospital at the expense of the plaintiff because they had a "countervailing economic incentive" from the plaintiff who was leasing office space to them and they wanted to avoid eviction. *HTI*, 960 F. Supp. 1104, 1137 ("[T]he Court finds as fact that [the upstream physicians' practice's] current office lease arrangement with [the plaintiff] . . . creates a countervailing economic incentive for the physicians to maintain a cooperative association with [the plaintiff]. . . . Thus, in light of [the

upstream physicians' practice's] need for office space [and their] concerns that [the plaintiff], as lessor, might exercise its eviction powers [and other medical treatment-related factors]" the court concluded the physicians would not steer patients to an affiliate hospital.) Suffice to say MCED test developers wield no such power over Illumina here. Accordingly, the Proposed Conclusion should be disregarded.

E. Complaint Counsel Disregards the Fact that NGS Costs Will be a Very Small Part of MCED Test Revenues Going Forward

81. Where, as here, the cost of the upstream input only represents price represents only a small percentage of the downstream product price, vertical foreclosure is not a concern. *See* George Raitt, The Metaphysics of Market Power: The Zero-sum Competition and Market Manipulation Approach 180 (2020) ("If the input is a relatively small part of the total costs of producing the downstream product, foreclosure would have little effect on downstream competition"); William P. Rogerson, *Modelling and Predicting the Competitive Effects of Vertical Mergers: The Bargaining Leverage over Rivals (BLR) Effect* 13, (February 28, 2020) ("[W]here the price charged by any particular upstream firm is small relative to the price of the downstream product that incorporates the input . . . even a relatively large percentage change in the price of an upstream good will result in a relatively small percentage change in the price of the downstream product, even if the entire upstream price increase is passed through to the downstream price. . . . [A] model which assumes that firms ignore these effects may still be relatively accurate even if firms do take account of these effects"); *cf. Fruehauf*, 603 F.2d at 354 (reversing Commission's order for divestiture in part because "neither the [upstream antiskid braking devices] ASBD market nor Fruehauf's [downstream] purchases in that market are likely to be significant")

Response to Proposed Conclusion No. 81

The Proposed Conclusion is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

The Proposed Conclusion is misleading and incomplete. The Proposed Conclusion cites one sentence from George Raitt, *The Metaphysics of Market Power: The Zero-Sum Competition and Market Manipulation Approach* (2020), to support the concept that foreclosing an input that is a small part of the total production costs of a downstream product would have "little effect on downstream competition." The Raitt textbook should be disregarded. According to the publisher's description of the textbook, it "offers a radical interpretation of market power" under

Australian competition law and therefore has no relevance to an assessment of antitrust economics as accepted by courts in the United States.

The Proposed Conclusion's reliance on Rogerson is also misplaced. The quote from Rogerson involves one of several justifications for assuming "input and output prices [of a video programming model] are set simultaneously." William P. Rogerson, *Modelling and Predicting the Competitive Effects of Vertical Mergers: The Bargaining Leverage over Rivals (BLR) Effect* 12-13, (Feb. 28, 2020). It is clear that the quote was not intended as a general statement, but rather to support an assumption in a stylized model from a different industry.

The Proposed Conclusion's cite to *Fruehauf* is also misleading. In *Fruehauf* the court never discussed the significance of the prices or costs relative to total revenues, rather it discussed whether the *degree of potential customer or supplier foreclosure* in the upstream or downstream markets, respectively, were "likely to be significant." *Fruehauf*, 603 F.dat 350. For these reasons, the Proposed Conclusion should be disregarded.

F. Complaint Counsel's Theory Ignores Intensifying Upstream Competition

82. A necessary condition for a vertical merger to harm competition in the relevant market is a limited ability by the merged firm's rivals to switch their purchases of the related product to sufficiently close substitutes. (PFF ¶ 916.) Thus, Complaint Counsel was required to establish that Illumina will control NGS platforms, and that there will be no viable substitutes (from the standpoint of MCED test developers that could potentially compete with Galleri) for Illumina's NGS platforms during the relevant time period. (PFF ¶ 916.1.) Complaint Counsel failed to make that showing.

Response to Proposed Conclusion No. 82

The Proposed Conclusion is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. [redacted] Consequently, the Proposed Conclusion should be disregarded.

83. In horizontal merger challenges, "by putting forward statistics to show that the proposed 'merger would produce a firm controlling an undue percentage share of the relevant market, and would result in a significant increase in the concentration of firms in that market,' the Government triggers a 'presumption' that the merger will substantially lessen competition." *AT&T I*, 310 F. Supp. 3d at 192. That presumption can then be defeated by the merging parties by showing that there is likely entry that prevents the presumption of harm based on the structural features of the horizontal market at issue. In vertical cases, no such presumption exists, and, therefore, the "timely, likely and sufficient" framework that Complaint Counsel seeks to import here does not apply. Instead, "[w]ith no presumption of harm in play, the Government . . . must make a 'fact-specific' showing that the effect of the proposed merger 'is likely to be anticompetitive.'" *Id*. Such a showing requires proving that competition will not prevent the combined firm from having an incentive and ability to foreclose rivals. As Complaint Counsel acknowledges, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" *United States v. Aetna, Inc.,* 240 F. Supp. 3d 79 (D.D.C. 2017) (internal citation omitted). Thus, it was Complaint Counsel's burden to demonstrate that Illumina has the ability and incentive to foreclose during the relevant timeframe—when any MCED test in development emerges as a likely rival to GRAIL, which is, at best, far in the future—and it failed to meet that burden, including because its theory cannot account for the surge of NGS investment and impending entry

Response to Proposed Conclusion No. 83

The Proposed Conclusion is misleading and incomplete. It misstates caselaw and misapplies legal standards to this case—making unsupported, conclusory claims about what constitutes the "proper timeframe" in the MCED testing market. As discussed in Complaint Counsel's post-trial reply brief, Respondents misconstrue the *Baker Hughes* burden-shifting framework's application to vertical mergers. *See* Complaint Counsel's Post-Trial Reply Brief §§ II.B, III.A. Moreover, as one of Respondents' heavily cited cases states, there is a *per se* rule that potential foreclosure "amount[s] to a violation of § 7" when "the share of the market foreclosed reaches monopoly proportions." *Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir.1979) (citations omitted); *see also Brown Shoe,* 370 U.S. at 328-29 (noting that "the Clayton Act will, of course, have been violated" where "the share of the market foreclosed is so large that it approaches monopoly proportions").

The Proposed Conclusion incorrectly argues that the application of the *Baker Hughes*

burden-shifting framework differs between horizontal and vertical cases because there is no relevant market concentration presumption in vertical cases. *See Baker Hughes*, 908 F.2d at 982-83. But the market concentration presumption merely provides one non-exclusive way in which the Government can meet its *prima facie* burden under *Baker Hughes*. The language courts use to describe the horizontal structural presumption indicates it is merely one way the Government can meet its *prima facie* burden. *See FTC v. Hackensack Meridian Health, Inc.*, 2021 WL 4145062 at *21 (D.N.J. Aug. 4, 2021) ("But even if the Court were to accept any of [defendants' alternative markets that eliminate the presumption of enhanced market power], direct evidence supports the conclusion that the merger will substantially lessen competition . . . ."); *Chi. Bridge*, 534 F.3d at 423 ("*Typically* the Government establishes a *prima facie* case by showing that the transaction in question will significantly increase market concentration, thereby creating a presumption that the transaction is likely to substantially lessen competition.") (emphasis added); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1081 (D.D.C. 1997) ("*One way* [to consider the probable effect of a merger] is to examine the concentration statistics and HHIs within the [relevant] markets.") (emphasis added).

Accordingly, the same *Baker Hughes* framework applies regardless of whether the Government meets its initial burden by showing a structural presumption or producing other evidence showing a likelihood of substantial lessening of competition. Respondents fail to articulate cogent reasons justifying departure from well-established precedent and requiring the Government to carry both its burden and Respondents' in the first instance.

The Proposed Conclusion mischaracterizes the district court opinion in *AT&T*. When the *AT&T* district court explicitly addressed *Baker Hughes*, it stated, "Defendants assert that the burden-shifting framework is inapplicable to vertical merger cases, where no market-

concentration-based presumption of harm attaches. As such, defendants argue that the Government has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case. I am skeptical of this position, both as a matter of law and logic." *AT&T*, 310 F. Supp. 3d at 191 n.17 (D.D.C.).

As with other rebuttals of Complaint Counsel's *prima facie* case under the *Baker Hughes* framework, Respondents bear the burden of presenting evidence that entry will restore the competitive intensity lost as a result of the Acquisition. *See In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *12 (F.T.C. Nov. 1, 2019) (citing *FTC v. H.J. Heinz Co.,* 246 F.3d 708, 715 n.7 (D.C. Cir. 2001)); *see also H&R Block*, 833 F. Supp. 2d at 73 (noting that defendants "carry the burden to show" that entry or expansion is sufficient "to fill the competitive void" that would result from the merger) (internal quotations omitted). As Complaint Counsel explained in its post-trial brief, the same principles dictating that Respondents must prove entry in horizontal cases similarly apply in vertical cases. Complaint Counsel's Post-Trial Brief § II.A.2. In *Ford Motor*, a vertical merger case, the Supreme Court assessed the defendant's argument that there were "a greater number of competitors" post-acquisition. 405 U.S. at 570 (noting that the seller of spark plug manufacturing assets to Ford subsequently constructed a new manufacturing facility and gained market share). Importantly, the Court analyzed the argument as one of the defendant's rebuttal points (in addition to the defendant's alleged procompetitive benefits)—rather than something the Government had a *prima facie* burden to disprove—and ultimately rejected the argument. *Id*. (concluding the acquisition nonetheless "aggravated an already oligopolistic market").

And like other rebuttals, once Complaint Counsel makes a *prima facie* case that there is a reasonable probability of competitive harm, Respondents must show entry or expansion "can

counteract anticompetitive effects that would otherwise be expected." *H&R Block*, 833 F. Supp. 2d at 73. Such entry or expansion must be "'timely, likely, and sufficient in its magnitude, character, and scope' to counteract a merger's anticompetitive effects." *Anthem*, 236 F. Supp. 3d at 222-24 (quoting *H&R Block*, 833 F. Supp. 2d at 73). Moreover, under the Commission's evidentiary rules, Respondents bear the burden of supporting those factual claims with evidence. *In re Altria Group, Inc. and Juul Labs, Inc.*, Initial Decision, Docket No. 9393, at 5 (F.T.C. Feb. 15, 2022) ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)). For these reasons, the Proposed Conclusion should be disregarded.

IV. COMPLAINT COUNSEL ERRS IN DISMISSING THE OPEN OFFER

84. Assuming, *arguendo*, that the Transaction would give Illumina an incentive and ability to foreclose GRAIL's putative rivals in the absence of any contractual commitments not to do so, the Open Offer prevents any possible anticompetitive harms.

Response to Proposed Conclusion No. 84

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Further, the Proposed Conclusion is incorrect and misleading to the extent it suggests that the Open Offer "prevents any possible anticompetitive harms." As Complaint Counsel explained thoroughly in its post-trial brief and post-trial reply brief, rather than "replac[ing] the competitive intensity" lost from the Acquisition, *Aetna*, 240 F. Supp. 3d at 60, [redacted] Therefore,

this Proposed Conclusion should be disregarded.

85. Courts adjudicating merger challenges frequently find proposed remedies like the Open Offer sufficient to address the alleged anticompetitive harms. *See, e.g., United States v. AT&T, Inc.* (*AT&T II*), 916 F.3d 1029, 1042–43 (D.C. Cir. 2019) (holding, in a vertical merger case, that "Turner Broadcasting's irrevocable offers of no-blackout arbitration agreements" made the merger "unlikely to afford Turner Broadcasting increased bargaining leverage", the government's primary theory of harm); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1298 (W.D. Mich. 1996) (holding that merging hospitals had successfully rebutted FTC's *prima facie* case and evidence in light of the hospitals' proposed "Community Commitment", which served as an "additional assurance that the merged entity would not exercise its market power to raise prices or otherwise injure the community"); *see also FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 304 (D.D.C. 2020) (holding that "any anticompetitive effects of the merger in the proposed Pacific Northwest geographic market are resolved by PeroxyChem's proposed divestiture of its Prince George plant"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 223, 225, 233 (S.D.N.Y. 2020) (holding that Defendants successfully rebutted Plaintiff States' *prima facie* case because the proposed remedies and conditions to the transaction "significantly reduce the concerns and persuasive force of Plaintiff States' market share statistics"); *FTC v. Atlantic Richfield Co.*, 549 F.2d 289, 299 (4th Cir. 1977) (holding that the FTC's claim that the merger would substantially lessen competition was rendered "moot" by subsequent post-merger agreement to divest certain assets).

Response to Proposed Conclusion No. 85

The Proposed Conclusion is incorrect and misleading to the extent it implies that these cases present "proposed remedies like the Open Offer." The Proposed Conclusion is incorrect because it cites to three cases ordering or approving *divestitures*, which are structural remedies not alike at all to the Open Offer. *See FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 304 (D.D.C. 2020) (holding that the anticompetitive effects of the merger were resolved by a proposed divestiture of the target's only plant in the market); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 225, 233 (S.D.N.Y. 2020) (concluding that the divestiture of Boost, "the most successful part of Sprint's business," reduced concerns of increased concentration); *FTC v. Atlantic Richfield Co.*, 549 F.2d 289, 299 (4th Cir. 1977) (affirming denial of injunction in uranium oxide merger because merged firm agreed to divest its only uranium oxide operation). It is no surprise that the bulk of the caselaw Respondents cite involves structural remedies as "[s]tructural remedies are preferred for Section 7 violations." *In re Evanston Northwestern*

Healthcare Corp., 2007 WL 2286195, at *77 (F.T.C. Aug. 6, 2007) (citing *du Pont 1961,* 366 U.S. at 329); *see also Otto Bock*, 2019 WL 2118886, at *53 (Chappell, A.L.J.) (citing *du Pont 1961*, 366 U.S. at 329) ("[C]omplete divestiture is generally the most appropriate way to restore competition lost through an unlawful acquisition."). Here, Respondents decidedly are not proposing a divestiture, or any sort of structural remedy, but are instead arguing for a complex behavioral remedy rife with flaws and loopholes, and wholly insufficient to resolve the anticompetitive harms of the Acquisition.

The Proposed Conclusion is misleading to the extent it implies that the behavioral remedies in *AT&T* and *Butterworth* are "like the Open Offer." *See* Complaint Counsel's Post-Trial Reply Brief § IV.B. In *AT&T*, the Government alleged a very specific theory of harm—that the combined firm could more credibly threaten blackouts (meaning the distributor would not be able to display the merged firm's content) post-merger, thereby increasing prices to distributors, which would pass those higher prices on to consumers. *AT&T*, 310 F. Supp. 3d at 201 (D.D.C.); *AT&T*, 916 F.3d at 404–05 (D.C. Cir.) (reiterating that the theory of harm was limited to consumer price effects). The merging parties proposed arbitration agreements that they argued defeated the Government's theory of harm. The proposed arbitration agreements would prevent a blackout while arbitration was pending, thereby averting any content blackouts from taking place until the arbitrator made its ultimate decision. *Id.* at 217. After the district court found no "adequate basis to conclude that the challenged merger will lead to *any* raised costs on the part of distributors or consumers," the court then discussed the proposed arbitration agreements in a footnote, making clear that its discussion was *dicta* by calling the proposed arbitration agreements "extra icing on a cake already frosted." *Id.* at 241 n.51 ("Although they amount to 'extra icing on a cake already frosted,' there are even more reasons to be skeptical of

the Government's increased-leverage theory of competitive harm.") (quoting *Yates v. United States*, 135 S. Ct. 1074, 1093 (2015) (Kagan, J., dissenting)); *see also AT&T*, 916 F.3d at 1041.

While the adequacy of a remedy depends on the specific facts of a given case, the arbitration agreements proposed in *AT&T* are starkly different from the provisions of the Open Offer (which go well beyond a single arbitration provision). As an initial matter, the potential harm to be addressed in this case is not limited exclusively to downstream consumer price effects due to increased bargaining leverage. That fundamental difference alone renders Respondents' attempt to rely on *AT&T* unavailing. Moreover, even if the harms to be remedied were similar—which they are not—*AT&T* also involved very different arbitration agreements. First, in *AT&T*, potentially harmed customers would learn immediately of a threatened blackout from their direct negotiations with the merged firm and could commence arbitration at any point thereafter. 310 F. Supp. at 184, 200 (D.D.C.). [redacted]

Second, in *AT&T*, once a customer invokes arbitration, it should trigger a ban on any blackout until the arbitration concludes. 310 F. Supp. at 184 (D.D.C.); *see also AT&T*, 916 F. 3d at 1041 (D.C. Cir.). In other words, if the merged firm had threatened a blackout, and the threatened distributor invoked arbitration, the threatened harm would not take effect during arbitration.

[redacted]

[redacted] Finally, the district court in *AT&T* explained, again in *dicta*, that it "ha[d] reason to believe that, post-merger, AT&T will honor Turner's commitment to arbitrate" based on the "real-world effects" of similar arbitration provisions in Comcast-NBCU, *AT&T*, 310 F. Supp. 3d at 241 n.51 (D.D.C.), which involved a nearly identical market. *Compare* Complaint, United States v. Comcast Corp., No. 1:11-cv-00106, at ¶ 38 (D.D.C. 2011) ("video programming distribution"), *with AT&T*, 310 F. Supp. at 195 ("multichannel video distribution"). Here, Respondents even admit that an agreement like the Open Offer is completely novel to Illumina and the industry, *see* Resp. Post-Tr. Br. at 151-52, thus there is no real-world evidence to support its efficacy here. [redacted]

The proposed remedy in *Butterworth*, whose premise and holding has been cast into serious doubt by other courts, is inapposite here. In *Butterworth*, the court reviewed the horizontal merger of two nonprofit hospitals. *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285 (W.D. Mich. 1996). As part of their proposed remedy, the merging parties offered a

"Community Commitment," in which the hospitals offered certain assurances to freeze prices and serve the underserved and medically needy communities. *Id*. at 1298. While the court ultimately held, "under the unique circumstances of this case," that the merged firm would not use its market power to raise prices post-merger, in *part* due to the proposed Community Commitment, the court noted that "[o]f critical importance in the Court's evaluation of the evidence" was the fact that "nonprofit hospitals operated differently in highly-concentrated markets than do profit-maximizing firms." *Id*. at 1298, 1302-03. The court acknowledged the FTC's concerns about the Community Commitment and noted that "[i]t is difficult to conceive of any commitment of this nature that would provide failsafe assurances to the community," but ultimately concluded that "nonprofit hospitals may be treated differently under the antitrust laws." *Id.* at 1298. Illumina is *not* a nonprofit business; it is a profit-maximizing firm, a difference of "critical importance" that undergirds the ruling of the *Butterworth* court. Thus, even if the *Butterworth* court's reasoning were valid, it would be inapplicable here. As Illumina's CEO testified at trial, Illumina owes a duty to its shareholders, which includes a duty to maximize the company's revenues. (deSouza (Illumina) Tr. 2193); (CCFF ¶ 6086). Moreover, even if price assurances, like those in *Butterworth*, were somehow sufficient to resolve concerns of increased prices post-merger, [redacted] Therefore, this Proposed Conclusion should be disregarded.

86. The audit and arbitration provisions have also been recognized in other cases. Together, these enforcement provisions help guarantee that the Open Offer "will have real world

effects" and put Illumina's "'money where [its] mouth is' in showing that the proposed merger, far from being aimed at 'doing any of the things that the government alleges,' is instead a 'vision deal' being pursued to achieve 'lower prices, improved quality, enhanced service, and new products.'" *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019).

Response to Proposed Conclusion No. 86

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded. Moreover, Respondents' conclusion that "[t]he audit and arbitration provisions have also been recognized in other cases" is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2.

[redacted] While the quote Respondents cite makes little sense in the context of the Acquisition, for the reasons described in Response to Proposed Conclusion No. 85, the comparison to the arbitration provision in *AT&T* is inapposite. [redacted]

[redacted] Therefore, this Proposed Conclusion should be disregarded.

87. The Second Circuit confronted a similar situation in *Fruehauf Corp. v. FTC*. 603 F.2d 345 (1979). There, a manufacturer of truck trailers, Fruehauf Corporation ("Fruehauf"), acquired Kelsey-Hayes Company ("Kelsey"), one of Fruehauf's suppliers of heavy-duty wheels ("HDWs"). *Id.* at 347. After the acquisition, Fruehauf promised that Kelsey would continue its historic practice of allocating supply shortages pro rata among all of its customers. *Id.* at 355. The Court explained that while "[o]ne might reasonably question the weight to be given to [Fruehauf's] self-serving assurances that Kelsey would allocate [p]ro rata if the need arose", Fruehauf's promises "need not rest upon some philosophical commitment to egalitarianism since it could also make sound business sense. If Kelsey deprived its regular customers of a proportionate share of HDWs in times of shortage it would risk their retaliating by shifting to competing suppliers not only their purchases of HDWs but of other products presently bought from Kelsey, which could cause it greater economic harm." *Id.* at 355. In part based on this reasoning, the Court held that the merger was not substantially likely to lessen competition. *Id.* Similarly here, the promises Illumina has made in the Open Offer "need not rest upon some philosophical commitment to egalitarianism" because they "make sound business sense" given that customers could retaliate against any breach of the Open Offer by "shifting to competing suppliers".

Response to Proposed Conclusion No. 87

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded.

The Proposed Conclusion is misleading to the extent it implies that Illumina's post-Acquisition incentives are similar to those described in *Fruehauf*. There the Court explained that it made "sound business sense" for the supplier to continuing serving its customers fairly because otherwise "it would risk their retaliating by shifting to competing suppliers." *Fruehauf*, 603 F.2d at 355. [redacted]

Accordingly, here, it makes "sound business sense" for Illumina to use its tools to entrench Grail

as the leader in the MCED test market and reap the profits for its shareholders.

88. Now that Illumina has made the Open Offer available to its customers, it cannot revoke it. The Open Offer clearly states that "[t]his irrevocable offer is binding on Illumina." (PFF ¶ 994.1.) Under New York contract law, which governs the Open Offer (PFF ¶ 994.1), Illumina is "firmly bound to hold [the Open Offer] open for the agreed time" of six years from the close of the Transaction. *Silverstein v. United Cerebral Palsy Ass'n of Westchester Cnty.*, 232 N.Y.S.2d 968, 968 (N.Y. App. Div. 1st Dep't 1962). If Illumina attempted to revoke the Open Offer prior to the end of the six-year term, customers could also sue Illumina under the promissory estoppel doctrine because the Open Offer is a clear and unambiguous promise, *see Ripple's of Clearview, Inc. v. Le Havre Assocs.*, 452 N.Y.S.2d 447, 449 (N.Y. App. Div. 2d Dep't 1982), and it is reasonably foreseeable that current or prospective customers of Illumina would rely on the commitments set forth in the Open Offer, *see Villnave Constr. Servs., Inc. v. Crossgates Mall Gen. Co. Newco, LLC*, 1612 N.Y.S.3d 480, 486 (N.Y. App. Div. 3d Dep't 2022). Illumina executives have made several public commitments to the Open Offer, including under oath at this trial, thus giving reasons even beyond New York contract law for Illumina to adhere to the Open Offer. (PFF ¶ 994.2.) Accordingly, Illumina is bound to hold the Open Offer open for six years after the close of the Transaction.

Response to Proposed Conclusion No. 88

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded.

The Proposed Conclusion is incorrect and misleading to the extent it implies that under New York Law, Illumina is "firmly bound to hold [the Open Offer] open for the agreed time." *Silverstein v. United Cerebral Palsy Ass'n of Westchester Cnty.*, 232 N.Y.S.2d 968, 970 (N.Y. App. Div. 1st Dep't 1962). Respondents cite only to *Silverstein* for this proposition but provide an incomplete quote. The court merely says that the "offeror *may* be firmly bound to hold his offer open for the agreed time" and that this is among the "issues which should be thoroughly explored on a trial." *Id.* at 970, 973(emphasis added). Thus, the *Silverstein* court does not say what Respondents claim and this Proposed Conclusion should be disregarded.

The Proposed Conclusion is misleading to the extent it implies that Illumina cannot breach its commitment not to revoke the Open Offer. As [redacted]

[redacted]

[redacted]

The Proposed Conclusion is misleading to the extent it implies that there will be no harm to customers to "sue Illumina under the promissory estoppel doctrine." [redacted] Therefore, this Proposed Conclusion should be disregarded.

89. The Open Offer's provisions are consistent with consent decrees adopted by the FTC in the past. (PFF ¶¶ 1000.3, 1103.3); *see, e.g.*, *Broadcom Inc.*, FTC Docket No. C-4622 (Aug. 17, 2017); *Evanston Northwestern Healthcare Corp.*, FTC Docket No. 9315 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Docket No. C-4652 (June 5, 2018); *PepsiCo, Inc.*, FTC Docket No. C-4301 (Sept. 27, 2010); *Sycamore Partners II*, FTC Docket No. C-4667 (Jan. 25, 2019). Complaint Counsel has provided no compelling reason why Illumina's Proposed Consent Order's terms differ from those of past consent decrees in a way that suggests the Proposed Consent Order would be less effective.

Response to Proposed Conclusion No. 89

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded.

The Proposed Conclusion is vague as to what aspects of the consent decrees listed are "consistent" with the Open Offer's provisions.

The Proposed Conclusion is misleading and irrelevant. The Commission's decision to accept a remedy or block a transaction is based on the facts of the particular matter at hand. In fact, over the past couple of years, the Commission has also sued to block several other vertical mergers. *See* Complaint, *In re Nvidia Corp., Softbank Group Corp., and Arm, Ltd.*, Docket No. 9404 (F.T.C. Dec. 2, 2021); Complaint, *In re Lockheed Martin Corp. and Aerojet Rocketdyne Holdings, Inc.*, Docket No. 9405 (F.T.C. Jan. 25, 2022). The operative question is not what the Commission has done in the past; it is whether the Respondents' Open Offer fully restores the competitive status quo that existed prior to the merger. For all the reasons stated in Complaint Counsel's post-trial briefing, it does not. *See* Complaint Counsel's Post-Trial Brief § II.F.3; Complaint Counsel's Post-Trial Reply Brief § IV. Therefore, this Proposed Conclusion should be disregarded.

90. Even aside from the Open Offer's formal provisions, extrinsic aspects of the Open Offer help ensure that Illumina will abide by its terms. (PFF ¶ 998.) Accordingly, it would be a mistake "to conclude that [Illumina] would (much less could) retreat from the commitment [of the Open Offer] in light of the apparent reputational costs of doing so—costs that would imperil future negotiations in a marketplace with repeat players." *AT&T I*, 310 F. Supp. 3d at 241 n.51. [redacted]

Response to Proposed Conclusion No. 90

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded. Moreover, it is unsupported by any legal authority or record evidence—but for a quote from *AT&T* that Respondents distort to

fit this case—as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is vague as to what "extrinsic aspects of the Open Offer" means and how these "extrinsic aspects" will help ensure that Illumina will abide by the Open Offer's terms.

The Proposed Conclusion is misleading to the extent it implies [redacted]

The Proposed Conclusion is against the weight of the evidence to the extent it implies that Illumina cares about its reputation or has a good reputation with customers. The evidence shows that Illumina's reputation among its customers is already poor. [redacted]

[redacted]

Additionally, Illumina cares less about its reputation because customers have nowhere else to go and their actions to foreclose rivals may go undetected. [redacted]

[redacted]

Lastly, Illumina has acknowledged that its reputation could suffer by closing the transaction in Europe but did it anyway. Illumina disclosed that consummating the transaction when it did could lead to "other adverse consequences to, among other things, its reputation[.]" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021)); *see also* (deSouza (Illumina) Tr. 2236-37) (stating that Illumina decided to close the transaction despite the potential risk to its reputation). Therefore, this Court should disregard the Proposed Conclusion.

91. Consent decrees are effective measures for resolving antitrust disputes and have been used by the FTC and other regulatory agencies for many years. (PFF ¶ 1072.1.) The Open Offer's provisions are consistent with consent decrees adopted by the FTC in the past. (PFF ¶¶ 1000.3, 1103.3); *see, e.g.*, *Broadcom Inc.*, FTC Docket No. C-4622 (Aug. 17, 2017); *Evanston Northwestern Healthcare Corp.*, FTC Docket No. 9315 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Docket No. C-4652 (June 5, 2018); *PepsiCo, Inc.*, FTC Docket No. C-4301 (Sept. 27, 2010); *Sycamore Partners II*, FTC Docket No. C-4667 (Jan. 25, 2019).

Response to Proposed Conclusion No. 91

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded. Moreover, it is essentially the same proposed conclusion as Proposed Conclusion No. 89.

The Proposed Conclusion is vague as to what aspects of the consent decrees listed are "consistent" with the Open Offer's provisions.

The Proposed Conclusion is misleading and irrelevant. The Commission's decision to accept a remedy or block a transaction is based on the facts of the particular matter at hand. In fact, over the past couple of years, the Commission has also sued to block several other vertical mergers. *See* Complaint, *In re Nvidia Corp., Softbank Group Corp., and Arm, Ltd.*, Docket No. 9404 (F.T.C. Dec. 2, 2021); Complaint, *In re Lockheed Martin Corp. and Aerojet Rocketdyne Holdings, Inc.*, Docket No. 9405 (F.T.C. Jan. 25, 2022). The operative question is not what the Commission has done in the past; it is whether the Respondents' Open Offer fully restores the

competitive status quo that existed prior to the merger. For all the reasons stated in Complaint Counsel's post-trial briefing, it does not. *See* Complaint Counsel's Post-Trial Brief § II.F.3; Complaint Counsel's Post-Trial Reply Brief § IV. Therefore, this Proposed Conclusion should be disregarded.

92. Consent orders or judgments subject to certain conditions are especially appropriate when, as here, defendants are willing to be legally bound by such orders or conditions. *See, e.g.*, *Butterworth*, 946 F. Supp. at 1298 (denying plaintiff's motion for injunction when "[d]efendants [were] willing to enter into a consent decree making the Community Commitment legally binding") (consent decree signed by court one month later); *United States v. Comcast Corp.*, 808 F. Supp. 2d. 145 (D.D.C. 2011) (approving merger where "defendants agreed to abide by the provisions of a proposed Final Judgment that would allow the merger to go forward, while also putting into place certain remedies for what the Government alleged was anti-competitive behavior") (final judgment entered on same day); *Anaconda Co. v. Crane Co.*, 411 F. Supp. 1210, 1218 (S.D.N.Y. 1975) (denying plaintiff's request for preliminary injunction in light of defendant's consent order that the Court determined was "sufficiently broad to prohibit any unilateral actions by Crane . . . which may have the effect of lessening competition with Anaconda"); *AT&T II*, 916 F.3d at 1041 (affirming the district court's approval of merger given defendant's voluntary offer of arbitration and no-blackout agreements that were "irrevocable" and "legally enforceable"); *United States v. Metro Denver Concrete Ass'n*, No. C-2478, 1972 WL 520 (D. Colo. Feb. 28, 1972) (final judgment entered pursuant to a consent decree executed by the defendants).

Response to Proposed Conclusion No. 92

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded.

The Proposed Conclusion is inaccurate and misleading to the extent it suggests that Respondents' contention that they are willing to be bound by the terms contained in an order is unique or probative. By definition, an order or judgment binds the respondent to its terms. The relevant inquiry is whether the terms of the order are sufficient to remediate past anticompetitive conduct and prevent its future repetition. Moreover, Respondents' claimed willingness to adhere to the requirements of the Open Offer must be assessed in light of the fact that they closed the Acquisition even though, as Illumina admitted in filings with the SEC, Illumina was prohibited from doing so during the "pendency of the European Commission's review" and would be

subject to "fines, penalties, remedies, or restrictions." (CCFF ¶¶ 218, 220-21). Respondents' disregard of their legal obligations (which were designed to protect competition) when it serves their self-interest raises doubt about their willingness to abide by an order. Therefore, this Proposed Conclusion should be disregarded.

V. THE BENEFITS OF THE TRANSACTION MORE THAN OFFSET THE ALLEGED HARM

93. Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the Transaction. The Transaction will lead to a number of significant efficiencies.

Response to Proposed Conclusion No. 93

First, this is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Second, Respondent's proposed conclusion is incorrect and contrary to the caselaw. First, no court has ever held that efficiencies or EDM rebutted a *prima facie* case that the merger is illegal. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies."); *see also Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (citations omitted).

Even assuming that the efficiencies defense is cognizable under the Clayton Act, the proposed conclusion is incorrect and contrary to the law because the caselaw is clear that

Respondents, not Complaint Counsel, bear the burden of producing "clear evidence showing that the merger will result in efficiencies that will *offset* the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hersey*, 838 F.3d at 350) (emphasis added); *see also FTC v. Hackensack Meridian Health, Inc.*, 2022 WL 840463, at *10 (3d Cir. 2022). In assessing such efficiency claims, courts have applied strict standards in their review. *Heinz*, 246 F.3d at 720-21; *H&R Block*, 833 F. Supp. 2d at 890. Specifically, "the court must undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721; *see also FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 72 (D.D.C. 2018); *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 72-73 (D.D.C. 2009). Accordingly, assuming *arguendo* that the efficiency defense is even potentially available, Respondents would bear the heavy burden to show that their efficiencies claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*;* *Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. To substantiate each efficiency, Respondents—not Complaint Counsel—would be required to demonstrate that "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger specific.'" *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89); *see also Hackensack*, 2022 WL 840463, at *10-11; *Horizontal Merger Guidelines* § 10. And, to demonstrate merger specificity,

Respondents would need to "present a type of cost saving that could not be achieved without the merger[.]" *Wilhelmsen*, 341 F. Supp. at 72; *see also Hackensack*, 2022 WL 840463, at *11 ("*i.e.*, the efficiencies cannot be achieved by either party alone").

[redacted] Therefore, the Proposed Conclusion should be disregarded.

A. The Reunion of Illumina and GRAIL Will Save Lives

94. For all the parties' disagreements, it is undisputed that accelerating consumer access to Galleri will save lives. (PFF ¶ 1117.) Respondents offered overwhelming evidence the Transaction will save lives and Complaint Counsel offered no credible evidence to the contrary.

Response to Proposed Conclusion No. 94

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Complaint Counsel does not dispute that MCED tests "are poised to turn the tide in the war on cancer" by "detect[ing] multiple cancers at early stages, leading to improved outcomes and saving lives." Complaint Counsel's Post-Trial Brief at 1. [redacted] Therefore, the Proposed Conclusion should be disregarded.

95. Courts have rejected challenges to mergers generating much less substantial healthcare benefits. *See*, *e.g.*, *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1032 (W.D. Mich. 1996) (concluding that "defendants have persuasively rebutted not only the FTC's prima facie case, but also the FTC's additional evidence of anticompetitive effect" as "[i]n the real world, hospitals are in the business of saving lives . . . Permitting defendant hospitals to achieve the efficiencies of scale that would clearly result from the proposed merger would enable the board of directors of the combined entity to continue the quest for establishment of world-class health facilities"); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 149 (E.D.N.Y. 1997) (holding that "the Government failed to prove that the merger of these hospitals will substantially lessen competition" after finding that the cost savings from the merger may be used "to fulfill [the defendants'] mission to provide high quality health care to economically disadvantaged and elderly members of the community"); *United States v. Carilion Health Sys.*, 717 F. Supp. 840, 846 (W.D. Va. 1989) (rejecting the government's Sherman Act merger challenge after finding that "the planned merger would probably improve the quality of health care in western Virginia").

Response to Proposed Conclusion No. 95

This Proposed Conclusion is incorrect and misleading. As both this Court and numerous Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies"); *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr.-Nampa*, 778 F.3d at 790. Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *Phila. Nat'l Bank*, 374 U.S. at 371 (internal quotations omitted); *see also FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Possible economies cannot be used as a defense to illegality."); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (internal citations omitted).

Consistent with this Court's observation in *Otto Bock*, none of the cases cited by

Respondent hold that the existence of efficiencies permits an otherwise unlawful merger—instead, in all of Respondents' cited cases the courts found that the plaintiffs had either failed to establish a *prima facie* case or had failed to demonstrate the merger would produce anticompetitive effects. *See Butterworth Health*, 946 F. Supp. at 1297 (holding that "a substantial increase in market concentration among nonprofit hospitals is not likely to result in price increases"); *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121, 145 (E.D.N.Y. 1997) ("Here, the Court finds that the merged entity will not have an undue share of the relevant product and geographic markets . . . . In the defined relevant product and geographic markets, the Government failed to prove, by a preponderance of the evidence, that the merged entity would, in all probability, produce an anti-competitive effect, by a price rise above competitive levels or a reduction in services."); *United States v. Carilion Health Sys.*, 707 F. Supp. 840, 849 (W.D. Va. 1989) (case involving the Sherman Act rather than the Clayton Act, and holding that "[t]he strength of remaining competition and the ease with which remaining competitors can further challenge defendants thus outweighs the increased market share defendants would acquire through their combination."). Moreover, Respondents' citation to Sherman Act Section 2 cases, however, obviously do not apply to this matter, which has been brought under Section 7 of the Clayton Act, as Congress intended Section 7 to have a lower standard than the Sherman Act. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 318 (1962) ("Congress rejected, as inappropriate to the problem it sought to remedy, the application to § 7 cases of the standards for judging the legality of business combinations adopted by the courts in dealing with cases arising under the Sherman Act, and which may have been applied to some early cases arising under original § 7.").

Finally, [redacted]

[redacted] Therefore, the Proposed Conclusion should be disregarded.

B. The Reunion of Illumina and GRAIL Will Accelerate Market Access to a Life Saving Test

96. The evidence showed the reunion of Illumina and GRAIL will substantially accelerate market access for Galleri. Complaint Counsel offered no persuasive evidence to the contrary.

Response to Proposed Conclusion No. 96

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Additionally, to demonstrate that an efficiency is cognizable, Respondents must demonstrate the following with respect to any claimed efficiencies:

> Cognizable efficiencies are defined as merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service. A cognizable efficiency claim must represent a type of cost saving that could not be achieved without the merger and the estimate of the predicted saving must be reasonably verifiable by an independent party. Moreover, the evidence must show that the claimed efficiencies would ultimately benefit customers.

Otto Bock, 2019 WL 2118886 at *50 (Chappell, A.L.J.). [redacted] Therefore, the Proposed Conclusion should be disregarded.

97. Dr. Navathe and Dr. Rothman argue that Illumina does not have the incentive to accelerate Galleri. (PFF ¶ 1134.7.) However, they are, of course, unqualified to speak to Illumina's state of mind. *Kruszka v. Novartis Pharm. Corp.*, 28 F. Supp. 3d 920, 937 (D. Minn. 2014) ("Expert testimony on 'the intent, motives, or state of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise.'"); *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 442 (E.D.N.Y. 2011) ("to the extent [an expert] seeks to opine on the 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred,' such testimony is inadmissible").

Response to Proposed Conclusion No. 97

The Proposed Conclusion is misleading and irrelevant. The Proposed Conclusion is misleading and irrelevant because neither Dr. Navathe nor Dr. Rothman offered an opinion regarding the state of mind of Illumina. The caselaw presumes that, as a result of the Acquisition, a combined Illumina/Grail will act as a single-profit maximizing entity. *See, e.g.*, *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768-69 (1984). The testimony of Drs. Navathe and Rothman bear on whether the Acquisition provides Illumina with such a financial incentive to foreclose or disadvantage Grail's rivals—[redacted]

[redacted]

Therefore, the Proposed Conclusion should be disregarded.

98. Increasing consumer access to a product has been found to outweigh purported anticompetitive harms in other cases—and in those cases, the product was not a test that saves lives. *See*, *e.g.*, *United States v. Crocker-Anglo Nat'l Bank*, 277 F. Supp. 133, 191 (N.D. Ca. 1967) ("[E]ven had a substantial lessening of competition occurred as a result of the merger of defendant banks, such anticompetitive effects were clearly outweighed in the public interest" in part because the merger "caused an immediate increase in the number of statewide banks competing within the state"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 208–09 (S.D.N.Y. 2020*)* (denying the government's request for an injunction to block the merger after considering that the proposed merger would allow "New T-Mobile to support additional subscribers at reduced marginal costs by creating "an 'inordinate amount' of new supply in the market"); *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 98 (N.D. Ill. 1981) (denying the FTC's request for injunction in part because the acquiring company, "an aggressive marketer of flame retardants internationally", would help the international market gain access to the acquired company's products).

Response to Proposed Conclusion No. 98

This Proposed Conclusion is incorrect and misleading. As both this Court and numerous

Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies"); *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr.-Nampa*, 778 F.3d at 790. Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *Phila. Nat'l Bank*, 374 U.S. at 371 (internal quotations omitted); *see also FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Possible economies cannot be used as a defense to illegality."); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (internal citations omitted).

Consistent with this Court's observation in *Otto Bock*, none of the cases cited by Respondents hold that the existence of efficiencies permits an otherwise unlawful merger—instead, in all of Respondents' cited cases the courts found that the plaintiffs had either failed to establish a *prima facie* case or had failed to demonstrate the merger would produce anticompetitive effects. *See United States v. Crocker-Anglo Nat'l Bank*, 277 F. Supp. 133, 138, 191 (N.D. Cal. 1967) (holding that "prior to and at the time of the merger, defendant banks were not in actual competition with each other in any economically significant section of the country[,] prior to and at the time of the merger, defendant banks were not in substantial potential competition with each other in any economically significant section of the country; [and that] the plaintiff has failed to prove by a preponderance of evidence that but for the merger

Crocker would have branched de novo into the Los Angeles metropolitan area or any economically significant banking market in which Citizens operated . . . [or] Citizens would have branched de novo into the San Francisco Bay area or any economically significant banking market in which Crocker operated"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020) (holding that efficiencies alone were not a "sole basis" to rebut the plaintiffs' cases, but instead, only in combination with evidence that "Sprint is a weakened competitor that is not likely to continue competing vigorously in the RMWTS Markets [and] evidence that the DOJ and FCC review of and remedies to the Proposed Merger, and particularly their collective efforts to establish DISH as a new vigorous competitor in the RMWTS Markets, ameliorate any remaining concerns of anticompetitive effect"); *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 87 (N.D. Ill. 1981) ("The competitive weakness of one of the two merging parties goes 'to the heart of the Government's statistical prima facie case,' and warrants a finding that no substantial lessening of competition is likely to occur in any market without reaching the issues of geographic and product markets.") (quoting *United States v. General Dynamics Corp.*, 415 U.S. 486, 508 (1974)).

Finally, [redacted]

Therefore, the Proposed Conclusion should be disregarded.

C. Reuniting Illumina and GRAIL Will Lead to R&D Efficiencies

99. In addition to accelerating market access, the Transaction will lead to significant R&D efficiencies, through the combination of GRAIL's expertise in methylation, data science and software development and Illumina's complementary expertise in sequencing and bioinformatics. (PFF ¶ 1136.) Respondents presented extensive fact testimony in support of this efficiency, whereas Complaint Counsel presented no fact witness to refute it. (PFF ¶ 1137.)

Response to Proposed Conclusion No. 99

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Additionally, to demonstrate that an efficiency is cognizable, Respondents must demonstrate the following with respect to any claimed efficiencies:

> Cognizable efficiencies are defined as merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service. A cognizable efficiency claim must represent a type of cost saving that could not be achieved without the merger and the estimate of the predicted saving must be reasonably verifiable by an independent party. Moreover, the evidence must show that the claimed efficiencies would ultimately benefit customers.

Otto Bock, 2019 WL 2118886 at *50 (Chappell, A.L.J.). [redacted] Therefore, the Proposed Conclusion should be disregarded.

100. Courts have rejected merger challenges based on the presence of R&D efficiencies. *See, e.g., Deutsche Telekom*, 439 F. Supp. 3d at 209 (finding that the proposed merger's efficiencies outweighed the anticompetitive harms in part because the merger would "reduce the cost and delay that T-Mobile would otherwise incur from building new towers for future network development", "accelerate mobile wireless carriers' provision of 5G" and "catalyze the earlier creation of new applications and services not currently possible in the 4G/LTE environment"); *AT&T I*, 310 F. Supp. 3d at 182–83, 191 n.17 (where the Court was "confident that defendants will achieve considerable efficiencies beyond those conceded by the Government" such as the "gains in innovation—particularly by way of a new programmatic advertising platform" before holding that the government failed to establish that the proposed merger violated Section 7 of the Clayton Act); *Great Lakes Chem. Corp.*, 528 F. Supp. at 94, 98 (finding that the procompetitive effects demonstrated the "absence of any lessening of competition", in part because "the acquisition will enhance critically needed research and

development in the industry [as the acquiring company] is an acknowledged leader in research and development.").

Response to Proposed Conclusion No. 100

This Proposed Conclusion is incorrect and misleading. As both this Court and numerous Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies"); *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr.-Nampa*, 778 F.3d at 790. Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *Phila. Nat'l Bank*, 374 U.S. at 371 (internal quotations omitted); *see also FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Possible economies cannot be used as a defense to illegality."); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (internal citations omitted).

Consistent with this Court's observation in *Otto Bock*, none of the cases cited by Respondent hold that the existence of efficiencies permits an otherwise unlawful merger—instead, in all of Respondents' cited cases the courts found that the plaintiffs had either failed to establish a *prima facie* case or had failed to demonstrate the merger would produce anticompetitive effects. *See AT&T*, 310 F. Supp. 3d at 199 (D.D.C.) ("Having heard and considered the evidence adduced at trial, I conclude that the Government has failed to clear the first hurdle of showing that the proposed merger is likely to increase Turner's bargaining

leverage in affiliate negotiations; I thus need not consider the separate legal question of whether any effects associated with the Government's increased-leverage theory would result in a substantial lessening of competition for purposes of the Clayton Act's prohibitions."); *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 87 (N.D. Ill. 1981) ("The competitive weakness of one of the two merging parties goes 'to the heart of the Government's statistical prima facie case,' and warrants a finding that no substantial lessening of competition is likely to occur in any market without reaching the issues of geographic and product markets.") (quoting *United States v. General Dynamics Corp*., 415 U.S. 486, 508 (1974)); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020) (holding that efficiencies alone were not a "sole basis" to rebut the plaintiffs' cases, but instead, only in combination with evidence that "Sprint is a weakened competitor that is not likely to continue competing vigorously in the RMWTS Markets [and] evidence that the DOJ and FCC review of and remedies to the Proposed Merger, and particularly their collective efforts to establish DISH as a new vigorous competitor in the RMWTS Markets, ameliorate any remaining concerns of anticompetitive effect").

Finally, [redacted] Therefore, the Proposed Conclusion should be disregarded.

D. The Reunion of Illumina and GRAIL Has Already Reduced GRAIL's Royalty Burden, Which Is a Benefit to Consumers

101. The Transaction will also lead to significant efficiencies by reducing royalties that GRAIL was required to pay Illumina before the Transaction. (PFF ¶ 1146.) Complaint Counsel presented no contrary evidence. (PFF ¶ 1148.5.)

Response to Proposed Conclusion No. 101

First, this is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Second, to demonstrate that an efficiency is cognizable, Respondents must demonstrate the following with respect to any claimed efficiencies:

> Cognizable efficiencies are defined as merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service. A cognizable efficiency claim must represent a type of cost saving that could not be achieved without the merger and the estimate of the predicted saving must be reasonably verifiable by an independent party. Moreover, the evidence must show that the claimed efficiencies would ultimately benefit customers.

Otto Bock, 2019 WL 2118886, at *50 (Chappell, A.L.J.). [redacted] Therefore, the Proposed Conclusion should be disregarded.

102. Nothing in Dr. Scott Morton's reports or in the reports of Complaint Counsel's other experts changes the fact that cost savings are a well-recognized justification for a merger. *See, e.g.*, *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 148–49 (finding that the Government failed to prove that the merger would substantially lessen competition because the cost savings of "approximately 25 to 30 million dollars per year" due to the merger "will ultimately result in benefits to the consumers"); *Advocacy Org. for Patients & Providers v. Mercy Health Servs*., 987 F. Supp. 967, 975 (E.D. Mich. 1997) (denying plaintiff's request to block a merger because "an injunction would delay or foreclose the realization of cost savings [resulting from the merger] in the amount of $15 million annually to the people of Michigan"); *Carilion Health Sys.*, 717 F. Supp. at 846 (holding that the government failed to meet its burden to block a merger after finding that "Defendants' board of directors could be expected to help insure that savings realized from the affiliation will be passed on to consumers"); *AT&T I*, 310 F. Supp. 3d 161, 164, 173 (D.D.C. 2018) (where the government conceded that the "vertical merger would result in hundreds of millions of dollars in annual cost savings to AT&T's customers" and "reduce the

'bargaining friction' inherent in the arm's-length affiliate negotiations . . . between traditional programmers and distributors" before the Court approved the merger).

Response to Proposed Conclusion No. 102

The Proposed Conclusion is irrelevant and incorrect. Respondents' assertion that claims in expert reports somehow impact the determination of the applicable legal standard for efficiencies is confusing—simply put, the relevant statutes and caselaw, not the opinions of any experts, governs whether cost savings may justify an otherwise anticompetitive merger. Thus, the first portion of Respondents' proposed conclusion is irrelevant.

The second portion of Respondents' Proposed Conclusion is incorrect and contrary to the applicable law. As both this Court and numerous Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies"); *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr.-Nampa*, 778 F.3d at 790. Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *Phila. Nat'l Bank*, 374 U.S. at 371 (internal quotations omitted); *see also FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Possible economies cannot be used as a defense to illegality."); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (internal citations omitted).

Consistent with this Court's observation in *Otto Bock*, none of the cases cited by

Respondents hold that the existence of efficiencies permits an otherwise unlawful merger—instead, in all of Respondents' cited cases the courts found that the plaintiffs had either failed to establish a *prima facie* case or had failed to demonstrate the merger would produce anticompetitive effects. *See, e.g.*, *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121, 145 (E.D.N.Y. 1997) ("Here, the Court finds that the merged entity will not have an undue share of the relevant product and geographic markets . . . . In the defined relevant product and geographic markets, the Government failed to prove, by a preponderance of the evidence, that the merged entity would, in all probability, produce an anti-competitive effect, by a price rise above competitive levels or a reduction in services."); *United States v. Carilion Health Sys.*, 707 F. Supp. 840, 849 (W.D. Va. 1989) (case involving the Sherman Act rather than the Clayton Act, and holding that "[t]he strength of remaining competition and the ease with which remaining competitors can further challenge defendants thus outweighs the increased market share defendants would acquire through their combination."); *AT&T*, 310 F. Supp. 3d at 199 (D.D.C.) ("Having heard and considered the evidence adduced at trial, I conclude that the Government has failed to clear the first hurdle of showing that the proposed merger is likely to increase Turner's bargaining leverage in affiliate negotiations; I thus need not consider the separate legal question of whether any effects associated with the Government's increased-leverage theory would result in a substantial lessening of competition for purposes of the Clayton Act's prohibitions."). Therefore, the Proposed Conclusion should be disregarded.

E. The Reunification of Illumina and GRAIL Will Result in Elimination of Double Marginalization

103. Respondents offered overwhelming evidence that the Transaction will lead to the elimination of double marginalization. Complaint Counsel does not present any factual testimony or other evidence suggesting that there were not two margins prior to the Transaction or that the elimination of double marginalization will not be achieved. (PFF ¶ 1155.1.)

Response to Proposed Conclusion No. 103

First, this is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Second, to demonstrate that an efficiency is cognizable, Respondents must demonstrate the following with respect to any claimed efficiencies:

> Cognizable efficiencies are defined as merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service. A cognizable efficiency claim must represent a type of cost saving that could not be achieved without the merger and the estimate of the predicted saving must be reasonably verifiable by an independent party. Moreover, the evidence must show that the claimed efficiencies would ultimately benefit customers.

Otto Bock, 2019 WL 2118886, at *50 (Chappell, A.L.J.). [redacted] Therefore, the Proposed Conclusion should be disregarded.

104. Contrary to Complaint Counsel's present view, the elimination of double marginalization is a well-accepted efficiency of vertical integrations, as numerous courts have recognized. *See*, *e.g.*, *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 465 (7th Cir. 2020) (interpreting *Port Dock & Stone Corp. v. Oldcastle Northeast, Inc.*, 507 F.3d 117 (2d Cir. 2007)—which affirmed the district court's dismissal of the plaintiff's complaint against a vertical integration—as an illustration of elimination of double marginalization); *Alberta Gas Chems Ltd. v. E.I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1247 (3d Cir. 1987) ("Because of post-merger efficiencies allowing [a firm] to purchase the acquiring company's output at a better price than in the marketplace, the acquired company's purchasing costs would fall—a procompetitive benefit capable of being passed on via lower prices for its products. Thus, in this scenario, post-merger self-dealing could result in efficiencies reflected in lower prices to the ultimate consumer") (holding that the plaintiff failed to present evidence of antitrust injury); *U.S. v. AT&T Inc.*, 310 F. Supp. 3d 161, 193, 197 (2018) ("[T]he Government concedes that this case implicates one 'standard benefit' associated with vertical mergers: the elimination of double

marginalization ('EDM')") (finding that the Government failed to prove that the merger would substantially lessen competition).

Response to Proposed Conclusion No. 104

The Proposed Conclusion is inaccurate and misleading. Respondents admit that EDM is an efficiency. *See* Resp. Post-Tr. Br. at 213-14 (describing their EDM claim as an "efficiency"); *see also* CC Post Tr. Br. § II.F.2.b. As both this Court and numerous Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies"); *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr.-Nampa*, 778 F.3d at 790. Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *Phila. Nat'l Bank*, 374 U.S. at 371 (internal quotations omitted); *see also FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Possible economies cannot be used as a defense to illegality."); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (internal citations omitted).

Consistent with this Court's observation in *Otto Bock*, none of the cases cited by Respondent hold that the existence of efficiencies permits an otherwise unlawful merger—instead, in all of Respondents' cited cases the courts found that the plaintiffs had either failed to establish a *prima facie* case or had failed to demonstrate the merger would produce anticompetitive effects. For example, in *AT&T*, the district court explained:

> [T]he Government has failed to clear the *first hurdle* of showing that the proposed merger is likely to increase Turner's bargaining leverage in affiliate negotiations; I thus need not consider the separate legal question of whether any effects associated with the Government's increased-leverage theory would result in a substantial lessening of competition for purposes of the Clayton Act's prohibitions.

310 F. Supp. 3d at 199 (emphasis added). The *AT&T* court made explicit that it did not need to reach the efficiencies claims because the Government failed to show anticompetitive effects. Moreover, to the extent the court discussed the existence of EDM in *AT&T*, it is because the government conceded that EDM would be generated in that transaction, *id.* at 197, whereas in this case, Complaint Counsel maintains that Respondents have failed to demonstrate that any EDM would be generated. Relatedly, Respondents rely on inapposite cases involving Section 2 claims, *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 465 (7th Cir. 2020) and *Albert Gas Chems. Ltd. v. E.I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1247 (3d Cir. 1987). Contrary to Respondents' suggestion, neither case involves an assessment of efficiencies. Instead, in both instances, the courts are noting that a vertically integrated firm does not violate Section 2 simply by eliminating margins when selling to itself. The cases are irrelevant and unhelpful. Therefore, the Proposed Conclusion should be disregarded.

F. The Reunion of Illumina and GRAIL Will Lead to Additional Efficiencies

105. The reunion of Illumina and GRAIL will also (1) lead to supply chain and operational efficiencies and (2) accelerate the international expansion of Galleri. (PFF ¶ 1156.)

Response to Proposed Conclusion No. 105

First, this is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Second, to demonstrate that an efficiency is cognizable, Respondents must demonstrate

the following with respect to any claimed efficiencies:

> Cognizable efficiencies are defined as merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service. A cognizable efficiency claim must represent a type of cost saving that could not be achieved without the merger and the estimate of the predicted saving must be reasonably verifiable by an independent party. Moreover, the evidence must show that the claimed efficiencies would ultimately benefit customers.

Otto Bock, 2019 WL 2118886, at *50 (Chappell, A.L.J.). But Respondents have not demonstrated the claimed supply chain and operational efficiencies are verifiable or merger specific, nor have Respondents substantiated that the alleged costs associated with these alleged savings. S*ee* Complaint Counsel's Post-Trial Reply Brief § V.D.3. Therefore, the Proposed Conclusion should be disregarded.

106. Courts have found cost savings arising from similar supply chain and operational efficiencies supporting the legality of mergers. *See*, *e.g.*, *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121, 147 (E.D.N.Y. 1997) (approving the merger because "[a]mong these merger-related savings are: a reduction in personnel in various departments of both hospitals . . .; some reduction in the cost of clinical laboratory services and medical supplies; claims recovery costs and utilities; laundry costs; in-house consulting services; and computer and information services."); *FTC v. Lab'y Corp. of Am.*, No. SACV 10-1873 AG MLGX, 2011 WL 3100372, at *10-11 (C.D. Ca. 2011) (denying the FTC's request for a preliminary injunction enjoining the merger) ("LabCorp presented evidence that the transaction will result in over $22 million annually in merger-specific efficiencies resulting from consolidating redundant facilities and employees and taking advantage of LabCorp's lower supply costs"); *FTC v. Butterworth*, 946 F. Supp. 1285, 1301 (W.D. Mich. 1996) (hospitals successfully rebutted the government's prima facie case because of evidence that "the proposed merger would result in significant efficiencies, in the form of capital expenditure avoidance and operating efficiencies, totaling in excess of $100 million" which "is, by any account, a substantial amount"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 209 (S.D.N.Y. 2020) (finding that the proposed merger's efficiencies outweighed the anticompetitive harms as the proposed merger would "save $4.2 billion in operating costs per year" and create savings "from streamlined advertising, the closing of 3,000 redundant retail stores, and reducing the costs of billing and other professional 'back office' services").

Response to Proposed Conclusion No. 106

This Proposed Conclusion is incorrect and misleading. As both this Court and numerous Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.)

(observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies"); *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr.-Nampa*, 778 F.3d at 790. Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *Phila. Nat'l Bank*, 374 U.S. at 371 (internal quotations omitted); *see also FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Possible economies cannot be used as a defense to illegality."); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (internal citations omitted). Consistent with this Court's observation in *Otto Bock*, none of the cases cited by Respondent hold that the existence of efficiencies permits an otherwise unlawful merger—instead, in all of Respondents' cited cases the courts found that the plaintiffs had either failed to establish a *prima facie* case or had failed to demonstrate the merger would produce anticompetitive effects. *See United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121, 145 (E.D.N.Y. 1997) ("Here, the Court finds that the merged entity will not have an undue share of the relevant product and geographic markets . . . . In the defined relevant product and geographic markets, the Government failed to prove, by a preponderance of the evidence, that the merged entity would, in all probability, produce an anti-competitive effect, by a price rise above competitive levels or a reduction in services."); *FTC v. Lab. Corp. of Am.*, No. SACV 10-1873 AG MLGX, 2011 WL 3100372, at *21 (C.D. Cal. Feb. 22, 2011) ("The FTC fails to establish its prima facie case. Even assuming a prima facie case, Defendants have presented sufficient rebuttal evidence, particularly

about new entrants."); *AT&T*, 310 F. Supp. 3d at 199 (D.D.C.) ("Having heard and considered the evidence adduced at trial, I conclude that the Government has failed to clear the first hurdle of showing that the proposed merger is likely to increase Turner's bargaining leverage in affiliate negotiations; I thus need not consider the separate legal question of whether any effects associated with the Government's increased-leverage theory would result in a substantial lessening of competition for purposes of the Clayton Act's prohibitions."); *Butterworth Health*, 946 F. Supp. at 1297 (holding that "a substantial increase in market concentration among nonprofit hospitals is not likely to result in price increases"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020) (holding that efficiencies alone were not a "sole basis" to rebut the plaintiffs' cases, but instead, only in combination with evidence that "Sprint is a weakened competitor that is not likely to continue competing vigorously in the RMWTS Markets [and] evidence that the DOJ and FCC review of and remedies to the Proposed Merger, and particularly their collective efforts to establish DISH as a new vigorous competitor in the RMWTS Markets, ameliorate any remaining concerns of anticompetitive effect"). Therefore, the Proposed Conclusion should be disregarded.

107. Courts have found acceleration of international expansion as supporting the legality of a merger. *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 98 (N.D. Ill. 1981) (denying the FTC's request for injunction against the proposed acquisition in part because "the acquisition will serve the national interest by promoting foreign trade. . . . Because Great Lakes plans to increase bromine-related sales abroad, the proposed transaction will result in increased exports and will benefit the nation's balance of payments and the economy as a whole. In this regard, courts have recognized that the "stimulation of additional international . . . activity is procompetitive and beneficial.'") (citations omitted). This Court should come to a similar conclusion.

Response to Proposed Conclusion No. 107

This Proposed Conclusion is incorrect and misleading. As both this Court and numerous Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.)

(observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies"); *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr.-Nampa*, 778 F.3d at 790. Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *Phila. Nat'l Bank*, 374 U.S. at 371 (internal quotations omitted); *see also FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Possible economies cannot be used as a defense to illegality."); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (internal citations omitted).

Consistent with this Court's observation in *Otto Bock*, the only case cited by Respondent does not hold that the existence of international efficiencies permits an otherwise unlawful merger. Instead, in *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 87 (N.D. Ill. 1981), the court held that "[t]he competitive weakness of one of the two merging parties goes 'to the heart of the Government's statistical prima facie case,' and warrants a finding that no substantial lessening of competition is likely to occur in any market without reaching the issues of geographic and product markets." (quoting *United States v. General Dynamics Corp*., 415 U.S. 486, 508 (1974)). Thus, the courts found that the plaintiffs had failed to establish a *prima facie* case or otherwise demonstrate the merger would produce anticompetitive effects.

Instead, the law is that "[a]n anticompetitive merger cannot be justified on the basis of asserted efficiencies outside the relevant market." *Otto Bock*, 2019 WL 2118886, at *49 (Chappell, A.L.J.); *see also Phila. Nat'l Bank,* 374 U.S. at 370; *Univ. Health*, 938 F.2d at 1222;

St. Alphonsus, 778 F.3d at 790; *Heinz*, 246 F.3d at 715.[1] Here, the relevant geographic market is the United States. *See* Complaint Counsel's Post-Trial Brief at 63-66; (CCFF ¶¶ 831-885). Thus, on its face, Respondents' claim that the Acquisition will increase "access to international markets" or "achieve regulatory and payor approvals" is irrelevant as those alleged benefits, which occur outside the United States, cannot offset competitive harm within the United States. *See Otto Bock*, 2019 WL 2118886, at *53 (Chappell, A.L.J.) ("Furthermore, the evidence is insufficient to justify a conclusion that the asserted efficiencies would benefit consumers in the United States, which is the relevant geographic market. Accordingly, Respondents' rebuttal argument based on efficiencies is rejected."). Therefore, the Proposed Conclusion should be disregarded.

G. The Benefits of the Transaction Are Merger Specific

108. Each of the efficiencies arising from the Transaction is merger specific because each was not, and could not have been, achieved but for the Transaction.

Response to Proposed Conclusion No. 108

First, this is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Second, Respondents' Proposed Conclusion that the Acquisition will result in a number of significant efficiencies that are merger specific is incorrect and contradicted by the weight of

[1] Respondents claim that "Courts have found acceleration of international expansion to be sufficient to justify a merger," Resp. Post-Tr. Br. at 224, citing a single case—*Great Lakes Chem.* But as explained *supra,* in *Great Lakes Chem.* the court actually found that "no substantial lessening of competition is likely to occur in any market without reaching the issues of geographic and product markets" because "[t]he competitive weakness of one of the two merging parties goes "to the heart of the Government's statistical prima facie case.'" 528 F. Supp. at 87 (quoting *General Dynamics Corp*., 415 U.S. at 508).

the evidence, which shows that Respondents have failed to demonstrate the merger-specificity of any of the claimed efficiencies. *See* Complaint Counsel's Post-Trial Reply Brief §§ V.B.2, V.C.2, V.D.2, V.E.3, V.F, V.G. Therefore, the Proposed Conclusion should be disregarded.

H. The Contentions of Complaint Counsel's Experts Do Not Rebut the Efficiencies

109. Complaint Counsel's only real response to the overwhelming and undisputed evidence that the Transaction will generate sizeable efficiencies is to fall back on its experts' assertions that the efficiencies are unsubstantiated. (PFF ¶ 1178.) That is no answer for multiple reasons.

Response to Proposed Conclusion No. 109

First, this is not a proposed conclusion of law because it is vague and does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. For example, it claims that the alleged "response" by Complaint Counsel is "no answer for multiple reasons" but neither identifies the "multiple reasons" nor cites any legal authority suggesting why Complaint Counsel's alleged "response" is not appropriate.

Second, the Proposed Conclusion is incorrect. Complaint Counsel has cited a substantial volume of evidence apart from Complaint Counsel's expert testimony establishing why Respondent has failed to demonstrate any cognizable efficiencies. *See generally* Complaint Counsel's Post-Trial Brief § II.F.2; Complaint Counsel's Post-Trial Reply Brief § V; (CCFF ¶¶ 5041-5966). Therefore, the Proposed Conclusion should be disregarded.

110. *First*, whether an efficiency is substantiated is a question for the Court; it is not an appropriate subject of expert testimony. *FTC v. Simple Health Plans LLC*, No. 18-CV-62593-, at *21–22 (S.D. Fla. Mar. 3, 2021) (excluding the expert's testimony because the expert was "opining about the sufficiency of [Plaintiff's] evidence" and thus impermissibly instructed the factfinder "about how to weigh the evidence") (quotations omitted); *In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61, 64 (S.D.N.Y. 2001) ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law."); *Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009) ("[A]n expert may never render conclusions of law.")

(citations omitted); *United States v. Thanh Quoc Hoang*, 891 F. Supp. 2d 1355, 1361-62 (M.D. Ga. 2012) ("[An expert] cannot offer testimony about the legal implications of evidence.").

Response to Proposed Conclusion No. 110

The Proposed Conclusion is inaccurate and misleading to the extent it suggests that Complaint Counsel, rather than Respondent, has the burden of substantiating any efficiency claims. As this Court has explained, because "[e]fficiencies are inherently 'difficult to verify and quantify,' . . . 'it is incumbent upon the merging firms to substantiate efficiency claims' so that it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.'" *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (quoting *Horizontal Merger Guidelines* § 10). The Proposed Conclusion also is inaccurate and misleading because it implies that Complaint Counsel's experts have offered legal conclusions, rather than merely pointing out as part of their expert opinions that *Respondents* failed to substantiate their claims through reasonably verifiable means. Finally, the Proposed Conclusion is irrelevant because regardless of whether Complaint Counsel's experts opined on the question of substantiation, the weight of the record evidence clearly demonstrates that Respondents failed to substantiate their efficiency claims. *See* Complaint Counsel's Post-Trial Reply Brief § V. Therefore, the Proposed Conclusion should be disregarded.

111. *Second*, the efficiencies are supported by fact testimony that Complaint Counsel's experts, for the most part, did not even consider. Their opinions amount to a critique of the opinions of Respondents' experts, whose opinions represent only a portion of Respondents' case.

Response to Proposed Conclusion No. 111

First, this is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as

required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. For example, it claims that the efficiencies are supported by facts, but cites no such facts.

Second, Respondents' proposed conclusion that the Acquisition will result in a number of significant efficiencies is incorrect and contradicted by the weight of the evidence, which shows that Respondents have failed to demonstrate any cognizable efficiencies. *See* Complaint Counsel's Post-Trial Reply Brief § V. Therefore, the Proposed Conclusion should be disregarded.

112. *Third*, Complaint Counsel's experts arrive at their conclusions by weighing the evidence, crediting the testimony that fit Complaint Counsel's thesis and dismissing the evidence that did not—again usurping the role of the Court. *United States v. Adams*, 271 F.3d 1236, 1245 (10th Cir. 2001) ("The credibility of witnesses is generally not an appropriate subject for expert testimony."); *Ellis v. Hobbs Police Dept.*, 472 F. Supp. 3d 1087, 1096 (D.N.M. 2020) (same); PFF ¶ 1178.1 (Scott Morton stating that she "weighed [witness statements] according to the information they had, the role they play in the company and the type of competition in which they are engaged.")).

Response to Proposed Conclusion No. 112

First, the Proposed Conclusion it is unsupported by any record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Specifically, Respondents claim that "Complaint Counsel's experts arrive at their conclusions by weighing the evidence, crediting the testimony that fit Complaint Counsel's thesis and dismissing the evidence that did not," but provide no citations to any examples of where Complaint Counsel's experts allegedly di so. Consequently, it should be disregarded.

Second, the Proposed Conclusion is inaccurate because it mischaracterizes the testimony by Complaint Counsel's experts. They did not usurp any role of the Court. Instead, Complaint Counsel's experts merely cited and detailed the various evidence which supported the bases of their opinions, as required by *this Court's* scheduling order. *See* Case Management Scheduling Order, *In re Illumina, Inc. and GRAIL, Inc.*, Docket No. 9401 ¶ 18(d) (Apr. 26, 2021)("Each

expert report shall include a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information relied on by the expert in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the expert; and the compensation to be paid for the study and testimony.").

Finally, the Proposed Conclusion is irrelevant because regardless of whether Complaint Counsel's experts opined on the question of substantiation, the weight of the record evidence clearly demonstrates that Respondents failed to substantiate their efficiency claims. *See* CC Reply Br. § V. Therefore, the Proposed Conclusion should be disregarded.

113. In sum, the Transaction will generate numerous efficiencies, including accelerating the adoption of Galleri, streamlining the supply chain, streamlining operations, accelerating international expansion, generating R&D efficiencies and, most importantly, saving lives. This evidence justifies allowing the Transaction, easily offsetting any alleged harm.

Response to Proposed Conclusion No. 113

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Additionally, Respondents' proposed conclusion that the Acquisition will result in a number of significant efficiencies is incorrect and contradicted by the weight of the evidence, which shows that Respondents have failed to demonstrate any cognizable efficiencies. *See* Complaint Counsel's Post-Trial Reply Brief § V. Therefore, the Proposed Conclusion should be disregarded.

VI. COMPLAINT COUNSEL'S CHALLENGE TO THE TRANSACTION VIOLATES THE U.S. CONSTITUTION

114. Complaint Counsel's challenge to the Transaction should be rejected because it violates Article II and the Due Process and Equal Protection Clauses of the U.S. Constitution. The FTC's case violates Article II, because FTC ALJs are afforded dual-layer protection from

presidential review. It violates the Due Process Clause, because the FTC is acting simultaneously as prosecutor, judge, and jury. And it violates the Equal Protection Clause, because it irrationally deprives Respondents of the structural and procedural protections they would possess in a challenge brought by the U.S. Department of Justice's Antitrust Division ("DOJ").

Response to Proposed Conclusion No. 114

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492-98 (2010)) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of

Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss*, In re LabMD, Inc.*, Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed [] ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted).

"It has long been decided that an administrative agency can combine investigative and adjudicatory functions." *In re N.C. State Bd. of Dental Examiners*, Docket No. 9343, 2011 WL

668509, at *6 (F.T.C. Feb. 16, 2011) (citing cases). In a 1929 opinion authored by Justice Brandeis, the Supreme Court characterized the Commission as "exercis[ing] under section 5 the functions of both prosecutor and judge." *FTC v. Klesner*, 280 U.S. 19, 27 (1929). Courts of appeals subsequently concluded that the Commission's multi-function structure satisfied due-process requirements, as Respondents tacitly acknowledge. *See, e.g.*, *FTC v. Cinderella Career & Finishing Schs., Inc.*, 404 F.2d 1308, 1315 (D.C. Cir. 1968) ("[I]t is well settled that a combination of investigative and judicial functions within an agency does not violate due process." (citation and quotation marks omitted)); *Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 79 (10th Cir. 1972) ("[T]his court pointed out in an early case . . . that the Federal Trade Commission combines the functions of investigator, prosecutor and judge and that Congress designed it in that manner. . . . [T]he courts have uniformly held that this feature does not make out an infringement of the due process clause of the Fifth Amendment.") (citation omitted); *see also* Resp. Post-Tr. Br. at 237 n.29 (citing these cases).

Any doubts about the constitutionality of the FTC's functional structure were resolved in *Withrow v. Larkin*, where the Supreme Court recognized that "the case law, both federal and state, generally rejects the idea that the combination of judging and investigating functions is a denial of due process." 421 U.S. 35, 52 (1975) (cleaned up). Distinguishing certain "situations" where "the probability of actual bias . . . is too high to be constitutionally tolerable," the Court reasoned that the "contention that the combination of investigative and adjudicative functions necessarily creates an unconstitutional risk of bias in administrative adjudication has a much more difficult burden of persuasion to carry." *Id.* at 47. Not only must such contentions "overcome a presumption of honesty and integrity in those serving as adjudicators," but they must also "convince that . . . conferring investigative and adjudicative powers on the same

individuals poses such a risk of actual bias or prejudgment that the practice must be forbidden." *Id.* The Court proceeded to list "prior decisions of this Court" where "[v]ery similar[] claims have been squarely rejected," beginning with the Court's decision to side with the FTC against a due-process challenge in *Cement Institute*. *Id.* at 47–48 (quoting *FTC v. Cement Institute*, 333 U.S. 683, 700-01 (1948)) (rejecting the claim that the Commission could be improperly biased "as a result of its prior official investigations").

Respondents' challenge rests on the assumption an FTC enforcement action and a DOJ enforcement action are mutually exclusive, such that the commencement of one prevents the pursuit of the other. But that assumption is wrong. The Commission recognized in *Otto Bock* that because both the FTC and DOJ share concurrent jurisdiction, "either agency could have brought an action against Respondent." 2019 WL 5957363, at *51 (citing *Cement Institute*, 333 U.S. at 694–95 (upholding concurrent jurisdiction to enforce statutes giving the agencies "cumulative remedies against activity detrimental to competition")). It follows that "[t]o the extent that the agencies choose to divide their workload, such that one brings an action rather than both doing so, this hardly gives a basis for complaint." *Id.* (citing *FTC v. AT&T Mobility LLC*, 883 F.3d 848, 862 (9th Cir. 2018) (having "two cops on the beat is nothing unusual")). Any differences in adjudicatory procedures or their outcomes therefore cannot give rise to any constitutional defects, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

Respondents here fail to explain how they have purportedly "been prejudiced by any differences in procedures" as between "federal court litigation versus the administrative litigation process." 2019 WL 5957363, at *50. Any differences in procedures between Part 3 adjudication and federal district court litigation are inconsequential, especially since many of the Part 3 rules

are modeled from the Federal Rules. As for appeals, legal conclusions by either the Commission or by a federal district court are reviewed *de novo* by the courts of appeal, and any difference between the standards for reviewing factual findings "is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome." *Dickinson v. Zurko*, 527 U.S. 150, 163 (1999). The most notable difference between appeals from federal district court decisions and Part 3 adjudicatory decisions cuts in Respondents' favor; that is, their ability to select which court of appeal will hear their appeal from an adverse decision. For these reasons, the Proposed Conclusion should be disregarded.

A. The FTC Violates Article II

115. In their challenge to Illumina's reunion with GRAIL, Complaint Counsel and the Commission have impinged upon the executive power vested in the President of the United States in violation of Article II of the U.S. Constitution.

Response to Proposed Conclusion No. 115

Complaint Counsel objects to the Proposed Conclusion because it is vague, confusing, misleading, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The

Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc*., Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate

investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted).

Respondents euphemistically refer to the Acquisition as a "reunion" between Grail and (its founder) Illumina as if this will inoculate the illegal transaction. *See, e.g.*, Response to Proposed Conclusion No. 115. Not only does this have no basis in law, *see Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768-69 (1984) (explaining, in a non-merger antitrust case, that when "two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit" it "deprives the marketplace of the independent centers of decision making that competition assumes and demands"), but this is not the virtuous reunion that Respondents claim. Rather, Illumina discarded Grail as soon as it became "untenable" for Illumina to continue to invest. (CCFF ¶ 44). Illumina knew that once it rid itself of majority ownership, Grail could either sink or swim—and if Grail succeeded, it would be an entirely different company than the fledgling start-up Illumina formed. Without help from Illumina, Grail and Illumina pursued their own interests, moving from a collaborative partnership to an arms-length supplier-customer relationship. Grail alone was able to raise funds, develop its MCED test, perform large-scale clinical studies, and market and sell its test to customers. *See* Complaint Counsel's Post-Trial Brief § I.B. Only now that Illumina no longer needs to invest the immense time and resources in the research and development of MCED tests does Illumina

want Grail back. Rather than immunize the potential harm from the Acquisition, the reunion story merely highlights the futility of Illumina's involvement in Grail's success and, accordingly, the baselessness of Respondents' procompetitive efficiency claims. For these reasons, the Proposed Conclusion should be disregarded.

116. Article II of the U.S. Constitution vests "[t]he executive Power . . . in a President of the United States of America", who must "take care that the laws be faithfully executed". U.S. Const. art II, § 1, cl. 1, § 3. In light of "[t]he impossibility that one man should be able to perform all the great business of the State", the Constitution provides for executive officers to "assist the supreme Magistrate in discharging the duties of his trust." 30 Writings of George Washington 334 (John C. Fitzpatrick ed., 1939).

Response to Proposed Conclusion No. 116

Complaint Counsel objects to the Proposed Conclusion because it is misleading, misrepresents the law, and contains propositions unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Moreover, because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a

"Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc*., Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform

only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

117. Since 1789, the Constitution has been understood to empower the President to keep these officers accountable by removing them from office if necessary. *See generally Myers v. United States*, 272 U.S. 52 (1926). The Supreme Court has recognized only two exceptions to the President's unrestricted removal power. In *Humphrey's Executor v. United States*, 295 U.S. 602 (1935), the Court held that Congress can, under certain circumstances, create independent agencies run by principal officers, whom the President may not remove at will but only for good cause. Likewise, in *United States v. Perkins*, 116 U.S. 483 (1886), and *Morrison v. Olson*, 487 U.S. 654 (1988), the Court sustained similar restrictions on the power of principal executive officers—themselves responsible to the President—to remove their own inferiors.

Response to Proposed Conclusion No. 117

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by

staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform

only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

118. In *Free Enterprise Fund v. Public. Co. Accounting. Oversight Board.*, the Court considered "whether these separate layers of protection may be combined"—that is, whether the President may "be restricted in his ability to remove a principal officer, who is in turn restricted in his ability to remove an inferior officer, even though that inferior officer determines the policy and enforces the laws of the United States". 561 U.S. 477, 483–84 (2010). The Court held that "such multilevel protection from removal is contrary to Article II's vesting of the executive power in the President". *Id.* at 484. The President cannot "take Care that the Laws be faithfully executed" if he cannot oversee the faithfulness of the officers who execute them. *Id.*

Response to Proposed Conclusion No. 118

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by

staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc*., Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform

only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

119. Here, Complaint Counsel's challenge runs afoul of Article II, because it seeks to undo the Transaction in a proceeding in which the President cannot "take Care that the Laws be faithfully executed", as he cannot adequately oversee the faithfulness of the officers who execute them. There is no question that FTC ALJs enjoy two layers of protection from the President. *See In re Otto Bock HealthCare N. Am., Inc.*, No. 9378, 2019 WL 5957363, at *49 (FTC Nov. 1, 2019) (acknowledging that FTC ALJs enjoy dual-layer protection from presidential review) (PFF ¶ 1181.) Like the Public Company Accounting Oversight Board ("PCAOB") members that the Court considered in *Free Enterprise Fund*, FTC ALJs may be removed only "for good cause established and determined by" someone other than the President, namely the Merit Systems Protection Board ("MSPB"). 5 U.S.C. § 7521(a). And like the SEC Commissioners who wielded limited removal power in *Free Enterprise Fund*, MSPB members may be removed by the President only for "inefficiency, neglect of duty, or malfeasance in office." 15 U.S.C. § 41.. "Neither the President, nor anyone directly responsible to him, nor even an officer whose conduct he may review only for good cause, has full control over" FTC ALJs. *Free Enter. Fund*, 561 U.S. at 496. These removal procedures are therefore "contrary to Article II's vesting of the executive power in the President." *Id.*

Response to Proposed Conclusion No. 119

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as

administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc*., Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime."

Id. at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

120. In prior challenges under Article II, the FTC has argued that the dual-level of protection afforded to FTC ALJs is of no constitutional moment because they are not "Officers of the United States". *See In re LabMD, Inc.*, No. 9357, Compl. Counsel's Opp'n to Resp't's Mot. to Amend Affirmative Defenses and to Dismiss this Proceeding 2-3 n.2-3 (Jul. 24, 2015). Following the Supreme Court's decision in *Lucia v. SEC*, 138 S. Ct. 2044 (2018), however, that argument is untenable. In *Lucia*, the Court held that SEC ALJs are "Officers of the United States". 138 S. Ct. at 2053–54. And there is no constitutionally significant difference between FTC ALJs and the SEC ALJs held to be "Officers of the United States" in *Lucia*. *Id.* Both may be "appoint[ed]" by their respective Commissions. 5 U.S.C. § 3105. Both "exercis[e] significant authority pursuant to the laws of the United States" by exercising the authority needed to ensure fair and orderly adversarial hearings. *Freytag v. Comm'r of Internal Rev.*, 501 U.S. 868, 881 (1991) (quoting *Buckley v. Valeo,* 424 U.S. 1, 126 (1976)). Both "take testimony", "conduct trials", "administer oaths, rule on motions, and generally 'regulat[e] the course of' a hearing, as well as the conduct of parties and counsel". *Lucia*, 138 S. Ct. at 2053 (quoting 17 C.F.R. §§ 201.111(c)) (SEC ALJs); *see* 16 C.F.R. § 3.42(c) (empowering FTC ALJs to, among other things, "receive evidence", "conduct . . . hearings", "administer oaths", "rule upon . . . motions", and "regulate the course of the hearings and the conduct of the parties and their counsel"). Both are empowered to "make and file initial decisions", which may then be appealed to the respective full Commission. 16 C.F.R. §§ 3.42(c)(9), 3.52(a)(1) (FTC ALJs); *see* 17 C.F.R. § 201.360(a)(1) (SEC ALJs). And both "have all powers necessary" to "dispos[e] of" the proceedings over which they preside. 16 C.F.R. § 3.42(c) (FTC ALJs); *see* 17 C.F.R. §§ 201.111, 200.14(a) (SEC ALJs).

Response to Proposed Conclusion No. 120

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's

Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

121. The Commission has relied on a footnote in *Free Enterprise Fund* to argue that its ALJs can be afforded dual-layer protection without violating Article II because FTC ALJs "perform adjudicative rather than enforcement or policymaking functions" and "possess purely recommendatory powers." *Free Enter. Fund*, 501 U.S. at 507 n.10; *see, e.g.*, *In re Axon Enter., Inc.*, No. 9389, Order Denying Resp't's Mot. to Disqualify the Administrative Law Judge 3-6 (Sept. 3, 2020). However, *Free Enterprise Fund* did not reach the question of whether ALJs are covered by its holding. The *Lucia* Court later made clear that they are. *See* 138 S. Ct. at 2049. And whether FTC ALJs perform adjudicative rather than enforcement or policymaking functions and possess recommendatory powers is not determinative after *Lucia*. *See id.* at 2060 (Breyer, J., concurring in part) (noting that if ALJs are "Officers", they may present a constitutional removal problem, since Congress has also provided ALJs with dual-layer removal protection—"just what *Free Enterprise Fund* interpreted the Constitution to forbid in the case of the Board members").

Response to Proposed Conclusion No. 121

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). As the FTC explained in *1-800 Contacts*, because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge

Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

122. In any case, FTC ALJs have both adjudicative and policymaking functions (like members of the PCAOB addressed in *Free Enterprise Fund*). *See* 501 U.S. at 507 n.10; *id.* at 3148 (citing 15 U.S.C. §§ 7213-7215 (2006)); *see also* Kevin M. Stack, *Agency Independence After PCAOB*, 32 Cardozo L. Rev. 2391, 2409-10 (2011). In addition to their adjudicative functions, FTC ALJs engage in some policymaking by conducting rulemaking proceedings and ensuring that the rulemaking proceeds in an orderly fashion. *See* 16 C.F.R. §1.13. The Supreme Court has recognized that all "judges do engage in policymaking at some level", by exercising discretion concerning issues of public importance. *Chisom v. Roemer*, 501 U.S. 380, 399 n.27 (1991) (citation omitted). Any claim that FTC ALJs possess "purely recommendatory powers" is incorrect. *Free Enter. Fund*, 501 U.S. at 507 n.10. While the Commission may review an ALJ's decision, the Commission may also decide not to review an ALJ decision at all, in which case the ALJ's decision becomes final. 16 C.F.R. § 3.52(a)(1).

Response to Proposed Conclusion No. 122

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc*., Docket No. 9357,

2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

122.1 The Commission in *In re Axon* suggested that the Commission's ability to modify or set aside an ALJ decision means that the Commission, rather than the ALJ, is responsible for final agency decisions. *In re Axon Enter., Inc.*, No. 9389, Order Denying Resp't's Mot. to Disqualify the Administrative Judge 5 (Sept. 3, 2020). However, *Free Enterprise Fund* presumes that PCAOB members do not possess "purely recommendatory powers". Since PCAOB members' issuance of rules and impositions of sanctions are subject to the SEC's approval and alteration, FTC ALJs also cannot possess

"purely recommendatory powers" simply because the Commission may review an ALJ's decision. 15 U.S.C. §§ 7217(b)-(c); *Free Enter. Fund*, 501 U.S. at 486.

Response to Proposed Conclusion No. 122.1

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its "holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers."

Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc.*, Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly *refused* to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

123. And in the past 26 years, the FTC has *never* reversed a decision in which an FTC ALJ found liability. Joshua D. Wright, Comm'r, FTC, Remarks at the Symposium on Section 5 of the Federal Trade Commission Act, *Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority* 6 (Feb. 26, 2015).

Response to Proposed Conclusion No. 123

This is not a Proposed Conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded. Moreover, these figures do not account for cases where, for example, the Commission declined to review an initial decision or dismissed counts of a complaint. *See e.g. McWane v. FTC*, 783 F.3d 814, 823 n.7 (11th Cir. 2015). Nor can "statistics alone" establish bias. *In re IBM Corp.*, 618 F.2d 923, 930 (2d Cir. 1980).

124. As the Supreme Court explained in *Seila L. LLC v. Consumer Financial Protection Bureau*, "[t]he Framers' constitutional strategy [wa]s straightforward: divide power everywhere except for the Presidency, and render the President directly accountable to the people through regular elections." 140 S. Ct. 2183, 2187 (2020). In that scheme, individual executive officials will still wield significant authority, but that authority will remain subject to the ongoing supervision and control of the elected President. Through the President's oversight, "the chain of dependence [is] preserved", so that "the lowest officers, the middle grade, and the highest" all "depend, as they ought, on the President, and the President on the community". 1 Annals of Cong. 499 (1789) (J. Madison). The FTC's dual-protection structure for ALJs contravenes this carefully balanced system by vesting significant governmental power in the hands of a single individual who is neither elected by the people nor meaningfully controlled (through the threat of removal) by someone who is.

Response to Proposed Conclusion No. 124

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Because an FTC ALJ "performs adjudicative rather than enforcement or policymaking functions, is subject to more Commission oversight, and is part of a well-established statutory structure that has been in place for more than 70 years," the ALJ "occupies a different role than the [board] found to be improperly insulated from presidential control in *Free Enterprise Fund*." *In re 1-800 Contacts, Inc.*, Docket No. 9372, 2018 WL 6078349, at *54 (F.T.C. Nov. 7, 2018) (citing *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 492–98, n.10 (2010) (noting that its

"holding also does not address that subset of independent agency employees who serve as administrative law judges" who, like the FTC ALJ, "of course perform adjudicative rather than enforcement or policymaking functions or possess purely recommendatory powers."). The Commission also distinguished *Lucia v. SEC*, another case on which Respondents rely, on the ground that FTC ALJs are appointed by the Commission as a "Head of Department" and not by staff. *1-800 Contacts*, 2018 WL 6078349, at *54 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2050 (2018)) (cleaned up). The Commission ultimately concluded in *1-800 Contacts*—and later reaffirmed in *Otto Bock*—that the ALJ's removability for "good cause" under the Administrative Procedure Act "gives the President a constitutionally adequate degree of control over ALJs." *Otto Bock*, 2019 WL 5957363, at *50 (citing *1-800 Contacts*, 2018 WL 6078349, at *54). Similarly, the Commission rejected a related challenge under Article II to the ALJ's appointment in LabMD, where the Commission concluded that "the Appointments Clause does not apply to the hiring of Commission administrative law judges" because they are not "inferior officers." Order Denying Resp. LabMD, Inc.'s Mot. to Dismiss, *In re LabMD, Inc*., Docket No. 9357, 2015 WL 5608167, at *2 (F.T.C. Sept. 14, 2015). The Commission proceeded to note that it had mooted the challenge when it "purely as a matter of discretion . . . ratified Judge Chappell's appointment as a Federal Trade Commission administrative law judge and as the Commission's Chief Administrative Law Judge." Id.

Accordingly, the Ninth Circuit's recent holding in *Decker Coal Co. v. Pehringer* that "properly appointed ALJs" in the Department of Labor "can adjudicate cases without trammeling on the President's executive power." 8 F.4th 1123, 1136 (9th Cir. 2021). A key factor in *Decker Coal* was that "[n]o statute mandates that the DOL employ ALJs in adjudicating . . . benefits claims," which means that Congress—as it also did with respect to FTC ALJs—"expressly

refused to require that these individuals be . . . insulated via a dual for-cause removal regime." *Id.* at 1133–34 (emphasis in original). Another factor was that the ALJs at issue, like FTC ALJs in Part 3 proceedings, "perform[] a purely adjudicatory function" and "cannot sua sponte initiate investigations or commence a . . . case." *Id.* at 1133. Quoting from then-Judge Kavanaugh's dissent in *Free Enterprise Fund*, the Ninth Circuit in *Decker Coal* noted that ALJs who "perform only adjudicatory functions that are subject to review by agency officials," as FTC ALJs do, "arguably would not be considered central to the functioning of the Executive Branch for purposes of the Article II removal precedents." *Id*. at 1133 (quoting *Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 699 n.8 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)) (internal quotation marks omitted). For these reasons, the Proposed Conclusion should be disregarded.

125. In addition, the single-layer constraint on the President's removal of the FTC Commissioners violates Article II. 15 U.S.C. § 41. The Solicitor General recently agreed in *Seila L. LLC*, that "[t]he reasoning for *Humphrey's Executor* [*v. United States*, 295 U.S. 602 (1935)]," which held that a single layer of good-cause protection is permissible under limited circumstances, "does not withstand careful analysis." *See* Br. for Resp't Supporting Vacatur, No. 19-7, 2019 WL 6727094, at *31, 45 (U.S. Dec. 9, 2019). Should the Court be inclined to revisit *Humphrey's Executor*, this case presents an appropriate opportunity to do so.

Response to Proposed Conclusion No. 125

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misrepresents the law. The Supreme Court squarely rejected this argument in *Humphrey's Executor v. United States*, 295 U.S. 602 (1935), which the Court declined to overrule in *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2198–201 (2020). For this reason, the Proposed Conclusion should be disregarded.

B. The FTC's Internal Administrative Process Violates the Due Process Clause

126. In addition to violating Article II, Complaint Counsel's challenge to the Transaction runs afoul of the Due Process Clause of the Fifth Amendment of the U.S. Constitution. "A fair trial in a fair tribunal is a basic requirement of due process". *Kaley v. United States*, 571 U.S. 320, 345 (2014) (quoting *In re Murchison*, 349 U.S. 133, 136 (1955)). This requirement applies to any adjudicative body, whether it be an administrative tribunal or a

court. *Gibson v. Berryhill*, 411 U.S. 564, 579 n.17 (1973). Not only is a biased decision maker constitutionally unacceptable but our system of law has also "always endeavored to prevent even the probability of unfairness." *Republican Party of Minn. v. White*, 536 U.S. 765, 815 (2002) (quoting *In re Murchison*, 349 U.S. at 136). In *Withrow v. Larkin*, the Supreme Court held that the combination of investigative and adjudicative functions does not necessarily constitute a due process violation. 421 U.S. 35, 58 (1975). However, the Court also made clear that there are circumstances in which the combination of investigative and adjudicative functions can constitute a due process violation, as there are situations "in which experience teaches that the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable". *Id.* at 47. In *Williams v. Pennsylvania*, the Supreme Court held that "an unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case". 579 U.S. 1, 1905 (2016).

Response to Proposed Conclusion No. 126

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misrepresents the law. "It has long been decided that an administrative agency can combine investigative and adjudicatory functions." *In re N.C. State Bd. of Dental Examiners*, Docket No. 9343, 2011 WL 668509, at *6 (F.T.C. Feb. 16, 2011) (citing cases). In a 1929 opinion authored by Justice Brandeis, the Supreme Court characterized the Commission as "exercis[ing] under section 5 the functions of both prosecutor and judge." *FTC v. Klesner*, 280 U.S. 19, 27 (1929). Courts of appeals subsequently concluded that the Commission's multi-function structure satisfied due-process requirements, as Respondents tacitly acknowledge. *See, e.g.*, *FTC v. Cinderella Career & Finishing Schs., Inc.*, 404 F.2d 1308, 1315 (D.C. Cir. 1968) ("[I]t is well settled that a combination of investigative and judicial functions within an agency does not violate due process." (citation and quotation marks omitted)); *Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 79 (10th Cir. 1972) ("[T]his court pointed out in an early case . . . that the Federal Trade Commission combines the functions of investigator, prosecutor and judge and that Congress designed it in that manner. . . . [T]he courts have uniformly held that this feature does not make out an infringement of the due process clause of the Fifth Amendment.") (citation omitted); *see also* Resp. Post-Tr. Br. at 237 n.29 (citing these cases).

Any doubts about the constitutionality of the FTC's functional structure were resolved in *Withrow v. Larkin*, where the Supreme Court recognized that "the case law, both federal and state, generally rejects the idea that the combination of judging and investigating functions is a denial of due process." 421 U.S. 35, 52 (1975) (cleaned up). Distinguishing certain "situations" where "the probability of actual bias . . . is too high to be constitutionally tolerable," the Court reasoned that the "contention that the combination of investigative and adjudicative functions necessarily creates an unconstitutional risk of bias in administrative adjudication has a much more difficult burden of persuasion to carry." *Id.* at 47. Not only must such contentions "overcome a presumption of honesty and integrity in those serving as adjudicators," but they must also "convince that . . . conferring investigative and adjudicative powers on the same individuals poses such a risk of actual bias or prejudgment that the practice must be forbidden." *Id.* The Court proceeded to list "prior decisions of this Court" where "[v]ery similar[] claims have been squarely rejected," beginning with the Court's decision to side with the FTC against a due-process challenge in *Cement Institute*. *Id.* at 47–48 (quoting *FTC v. Cement Institute*, 333 U.S. 683, 700-01 (1948)) (rejecting the claim that the Commission could be improperly biased "as a result of its prior official investigations"); *see also Gibson v. FTC*, 682 F.2d 554, 560 (5th Cir. 1982) ("The combination of investigative and judicial functions within an agency has been upheld against due process challenges, both in the context of the FTC and other agencies.").

This long line of cases affirming the constitutionality of the FTC's functional structure continues to make good sense. Section 5(b) of the FTC Act allows the Commission to initiate "a proceeding" if the Commission "shall have reason to believe" that a person "has been or is using any unfair method of competition" and that such a proceeding "would be to the interest of the public[.]" 15 U.S.C. § 45(b). Nothing in § 5(b) requires the Commission to prejudge the

outcome of such a proceeding before initiating it. To the contrary, "just as there is no logical inconsistency between a finding of probable cause and an acquittal in a criminal proceeding, there is no incompatibility between the agency filing a complaint based on probable cause and a subsequent decision, when all the evidence is in, that there has been no violation of the statute." *Withrow*, 421 U.S. at 57. Nor does any such "incompatibility" exist where, as here, the Commission seeks relevant information through knowledgeable witnesses, considers settlement proposals from Respondents, or voluntarily dismisses an action for a preliminary injunction before rendering a decision on the merits. *See id.* at 55 ("The mere exposure to evidence presented in nonadversary investigative procedures is insufficient in itself to impugn the fairness of the board members at a later adversary hearing.").

Respondents posit that the Supreme Court's decision in *Williams v. Pennsylvania*, 579 U.S. 1 (2016), which arose from a state supreme court justice's prior participation in a death-penalty prosecution, had repudiated nearly a century of case law governing the due-process standards for federal agency adjudication. This position rests on a misreading of *Williams* and a misapprehension of key differences between the criminal justice system and the FTC adjudication process. Far from overruling *Withrow* or "limit[ing]" its progeny Resp. Post-Tr. Br. at 237 n.29, the Court in *Williams* extended *Withrow* to hold that when a prosecutor authorized seeking the death penalty against a defendant, and then later heard a death-penalty appeal from the same defendant after becoming a state supreme court justice, the justice's participation in that appeal "gave rise to an unacceptable risk of actual bias." *Williams*, 579 U.S. at 14 (citing *Withrow*, 421 U.S. at 47). Unlike the justice at issue in *Williams*, the Commissioners adjudicating a Part 3 matter do not "serve[] as an advocate . . . in the case," nor do they have "a direct, personal role" in the conduct of Complaint Counsel. *Id.* at 9–10. Nothing in *Williams*

suggests any intent to change the settled standards under which federal courts have consistently upheld adjudicatory processes for agencies like the FTC.

Whatever remains of Respondents' due-process argument cannot survive their failure to show that any Commissioner, let alone the whole Commission, has actually prejudged the outcome in this matter. In the D.C. Circuit, an agency adjudicator may be subject to disqualification if "a disinterested observer may conclude that the agency has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." *Cinderella Career & Finishing Sch., Inc. v. FTC*, 425 F.2d 583, 591 (D.C. Cir. 1970) (cleaned up). Respondents do not even attempt to meet this standard. While Respondents allege that certain Commissioners sought information from a third party and considered Respondents' settlement proposal before voting to issue a complaint, no court has found that such run-of-the-mill conduct—in isolation or taken together—demonstrates unconstitutional prejudgment or bias. *Contra Withrow*, 421 U.S. at 50 n.16 (citing qualifying but inapposite examples); *see also Cement Institute*, 333 U.S. 701 (concluding that the parties had failed to show "that the minds of [the Commission's] members were irrevocably closed"). For these reasons, the Proposed Conclusion should be disregarded.

127. Some lower court cases before *Williams* can be read to authorize an agency to combine investigatory and adjudicatory functions, but they are clearly limited in the wake of *Williams*. *See, e.g.*, *Kennecott Copper Corp. v. FTC*, 467 F.2d 67 (10th Cir. 1972); *FTC v. Cinderella Career & Finishing Schs.*, 404 F.2d 1308 (D.C. Cir. 1968).

Response to Proposed Conclusion No. 127

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misrepresents the law. "It has long been decided that an administrative agency can combine investigative and adjudicatory functions." *In re N.C. State Bd. of Dental Examiners*, Docket No. 9343, 2011 WL 668509, at *6 (F.T.C. Feb. 16, 2011) (citing cases). In a

1929 opinion authored by Justice Brandeis, the Supreme Court characterized the Commission as "exercis[ing] under section 5 the functions of both prosecutor and judge." *FTC v. Klesner*, 280 U.S. 19, 27 (1929). Courts of appeals subsequently concluded that the Commission's multi-function structure satisfied due-process requirements, as Respondents tacitly acknowledge. *See, e.g.*, *FTC v. Cinderella Career & Finishing Schs., Inc.*, 404 F.2d 1308, 1315 (D.C. Cir. 1968) ("[I]t is well settled that a combination of investigative and judicial functions within an agency does not violate due process." (citation and quotation marks omitted)); *Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 79 (10th Cir. 1972) ("[T]his court pointed out in an early case . . . that the Federal Trade Commission combines the functions of investigator, prosecutor and judge and that Congress designed it in that manner. . . . [T]he courts have uniformly held that this feature does not make out an infringement of the due process clause of the Fifth Amendment.") (citation omitted); *see also* Resp. Post-Tr. Br. at 237 n.29 (citing these cases).

Any doubts about the constitutionality of the FTC's functional structure were resolved in *Withrow v. Larkin*, where the Supreme Court recognized that "the case law, both federal and state, generally rejects the idea that the combination of judging and investigating functions is a denial of due process." 421 U.S. 35, 52 (1975) (cleaned up). Distinguishing certain "situations" where "the probability of actual bias . . . is too high to be constitutionally tolerable," the Court reasoned that the "contention that the combination of investigative and adjudicative functions necessarily creates an unconstitutional risk of bias in administrative adjudication has a much more difficult burden of persuasion to carry." *Id.* at 47. Not only must such contentions "overcome a presumption of honesty and integrity in those serving as adjudicators," but they must also "convince that . . . conferring investigative and adjudicative powers on the same individuals poses such a risk of actual bias or prejudgment that the practice must be forbidden."

Id. The Court proceeded to list "prior decisions of this Court" where "[v]ery similar[] claims have been squarely rejected," beginning with the Court's decision to side with the FTC against a due-process challenge in *Cement Institute*. *Id.* at 47–48 (quoting *FTC v. Cement Institute*, 333 U.S. 683, 700-01 (1948)) (rejecting the claim that the Commission could be improperly biased "as a result of its prior official investigations"); *see also Gibson v. FTC*, 682 F.2d 554, 560 (5th Cir. 1982) ("The combination of investigative and judicial functions within an agency has been upheld against due process challenges, both in the context of the FTC and other agencies."). For these reasons, the Proposed Conclusion should be disregarded.

128. As in *Williams*, the FTC's challenge to the Transaction here creates an unconstitutional potential bias because the same people who voted out the complaint against Respondents—and have prosecuted the case against them—will adjudicate it.

Response to Proposed Conclusion No. 128

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded. Moreover, to the extent that does expound on any legal standard or proposition, it is misleading, incomplete, and misrepresents the law.

"It has long been decided that an administrative agency can combine investigative and adjudicatory functions." *In re N.C. State Bd. of Dental Examiners*, Docket No. 9343, 2011 WL 668509, at *6 (F.T.C. Feb. 16, 2011) (citing cases). In a 1929 opinion authored by Justice Brandeis, the Supreme Court characterized the Commission as "exercis[ing] under section 5 the functions of both prosecutor and judge." *FTC v. Klesner*, 280 U.S. 19, 27 (1929). Courts of appeals subsequently concluded that the Commission's multi-function structure satisfied due-process requirements, as Respondents tacitly acknowledge. *See, e.g.*, *FTC v. Cinderella Career & Finishing Schs., Inc.*, 404 F.2d 1308, 1315 (D.C. Cir. 1968) ("[I]t is well settled that a

combination of investigative and judicial functions within an agency does not violate due process." (citation and quotation marks omitted)); *Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 79 (10th Cir. 1972) ("[T]his court pointed out in an early case . . . that the Federal Trade Commission combines the functions of investigator, prosecutor and judge and that Congress designed it in that manner. . . . [T]he courts have uniformly held that this feature does not make out an infringement of the due process clause of the Fifth Amendment.") (citation omitted); *see also* Resp. Post-Tr. Br. at 237 n.29 (citing these cases).

Any doubts about the constitutionality of the FTC's functional structure were resolved in *Withrow v. Larkin*, where the Supreme Court recognized that "the case law, both federal and state, generally rejects the idea that the combination of judging and investigating functions is a denial of due process." 421 U.S. 35, 52 (1975) (cleaned up). Distinguishing certain "situations" where "the probability of actual bias . . . is too high to be constitutionally tolerable," the Court reasoned that the "contention that the combination of investigative and adjudicative functions necessarily creates an unconstitutional risk of bias in administrative adjudication has a much more difficult burden of persuasion to carry." *Id.* at 47. Not only must such contentions "overcome a presumption of honesty and integrity in those serving as adjudicators," but they must also "convince that . . . conferring investigative and adjudicative powers on the same individuals poses such a risk of actual bias or prejudgment that the practice must be forbidden." *Id.* The Court proceeded to list "prior decisions of this Court" where "[v]ery similar[] claims have been squarely rejected," beginning with the Court's decision to side with the FTC against a due-process challenge in *Cement Institute*. *Id.* at 47–48 (quoting *FTC v. Cement Institute*, 333 U.S. 683, 700-01 (1948)) (rejecting the claim that the Commission could be improperly biased "as a result of its prior official investigations"); *see also Gibson v. FTC*, 682 F.2d 554, 560 (5th

Cir. 1982) ("The combination of investigative and judicial functions within an agency has been upheld against due process challenges, both in the context of the FTC and other agencies.").

129. An accuser lacks the necessary neutrality to determine the merits of its own allegations. (PFF ¶ 1197.)

Response to Proposed Conclusion No. 129

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

130. As a former FTC Commissioner has acknowledged, once the Commission votes out a complaint, it finds in favor of itself 100% of the time. Joshua D. Wright, Comm'r, FTC, Remarks at the Symposium on Section 5 of the Federal Trade Commission Act, *Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority* 6 (Feb. 26, 2015).

Response to Proposed Conclusion No. 130

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded. Moreover, these figures do not account for cases where, for example, the Commission declined to review an initial decision or dismissed counts of a complaint. *See e.g. McWane v. FTC*, 783 F.3d 814, 823 n.7 (11th Cir. 2015). Nor can "statistics alone" establish bias. *In re IBM Corp.*, 618 F.2d 923, 930 (2d Cir. 1980).

C. The FTC's Structure and Procedural Rules Violate the Equal Protection Clause

131. The constitutional infirmity of Complaint Counsel's case is not limited to the fact that it violates Article II and the Due Process Clause. Complaint Counsel's challenge to the Transaction should also be rejected, because it violates the Equal Protection Clause of the U.S. Constitution.

Response to Proposed Conclusion No. 131

Complaint Counsel objects to the Proposed Conclusion because it is incomplete, misleading, and misrepresents the law. This argument has been rejected by the Commission and the courts.

At the threshold, Respondents make the same crucial misstep that doomed a similar equal-protection challenge in *Otto Bock*. Respondents' challenge rests on the assumption an FTC enforcement action and a DOJ enforcement action are mutually exclusive, such that the commencement of one prevents the pursuit of the other. But that assumption is wrong. The Commission recognized in *Otto Bock* that because both the FTC and DOJ share concurrent jurisdiction, "either agency could have brought an action against Respondent." 2019 WL 5957363, at *51 (citing *Cement Institute*, 333 U.S. at 694–95 (upholding concurrent jurisdiction to enforce statutes giving the agencies "cumulative remedies against activity detrimental to competition")). It follows that "[t]o the extent that the agencies choose to divide their workload, such that one brings an action rather than both doing so, this hardly gives a basis for complaint." *Id.* (citing *FTC v. AT&T Mobility LLC*, 883 F.3d 848, 862 (9th Cir. 2018) (having "two cops on the beat is nothing unusual")). Any differences in adjudicatory procedures or their outcomes therefore cannot give rise to any constitutional defects, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

Moreover, like the respondents in *Otto Bock*, Respondents here fail to explain how they have purportedly "been prejudiced by any differences in procedures" as between "federal court litigation versus the administrative litigation process." 2019 WL 5957363, at *50. Any differences in procedures between Part 3 adjudication and federal district court litigation are

inconsequential, especially since many of the Part 3 rules are modeled from the Federal Rules. As for appeals, legal conclusions by either the Commission or by a federal district court are reviewed *de novo* by the courts of appeal, and any difference between the standards for reviewing factual findings "is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome." *Dickinson v. Zurko*, 527 U.S. 150, 163 (1999). The most notable difference between appeals from federal district court decisions and Part 3 adjudicatory decisions cuts in Respondents' favor; that is, their ability to select which court of appeal will hear their appeal from an adverse decision. Respondents' claim that differences in adjudicatory procedures "can be outcome determinative," Resp. Post-Tr. Br. at 243, does not withstand scrutiny.

Even if there were any outcome-determinative differences between federal court litigation and FTC administrative adjudication, they would not amount to denial of equal protection. Respondents must show not only that the allocation of matters between DOJ and the FTC makes "classifications" that lead to disparate treatment, but also that the allocation arrangement lacks a "rational relationship to a legitimate governmental purpose." *Tennessee v. Lane*, 541 U.S. 509, 522 (2004). Here, the agencies' allocation arrangement serves the legitimate purpose of "[c]onserving government resources" by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. *Holt v. Howard*, 806 F.3d 1129, 1133 (8th Cir. 2015); *see also Giarratano v. Johnson*, 521 F.3d 298, 304 (4th Cir. 2008). Rational basis review is satisfied, foreclosing Respondents' equal-protection challenge. *See Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 272 (1979) ("When the basic classification is rationally based, uneven effects upon

particular groups within a class are ordinarily of no constitutional concern."). For these reasons, the Proposed Conclusion should be disregarded.

132. The Equal Protection Clause of the Fifth Amendment commands that the government shall not "deny to any person within its jurisdiction the equal protection of the laws". U.S. Const. amend. XIV, § 1; *U.S. v. Windsor,* 570 U.S. 744, 774 (2013) ("The liberty protected by the Fifth Amendment's Due Process Clause contains within it the prohibition against denying to any person the equal protection of the laws.") (citing *Bolling v. Sharpe*, 347 U.S. 497, 499–50 (1954)). "The guaranty of 'equal protection of the laws is a pledge of the protection of equal laws'". *Romer v. Evans*, 517 U.S. 620, 633-34 (1996) (quoting *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942)). Thus, the Equal Protection Clause protects against "arbitrary and irrational discrimination" by the Government, *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 83 (1988), and demands that "all persons similarly situated should be treated alike", *Tennessee v. Lane*, 541 U.S. 509, 522 (2004) (quoting *Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 439 (1985)). Any difference in treatment "run[s] afoul of the Equal Protection Clause" when there is no "rational relationship between the disparity of treatment and some legitimate governmental purpose". *Montgomery v. Louisiana*, 577 U.S. 190, 231 (2016).

Response to Proposed Conclusion No. 132

Complaint Counsel objects to the Proposed Conclusion because it is incomplete, misleading, and misrepresents the law. This argument has been rejected by the Commission and the courts.

At the threshold, Respondents make the same crucial misstep that doomed a similar equal-protection challenge in *Otto Bock*. Respondents' challenge rests on the assumption an FTC enforcement action and a DOJ enforcement action are mutually exclusive, such that the commencement of one prevents the pursuit of the other. But that assumption is wrong. The Commission recognized in *Otto Bock* that because both the FTC and DOJ share concurrent jurisdiction, "either agency could have brought an action against Respondent." 2019 WL 5957363, at *51 (citing *Cement Institute*, 333 U.S. at 694–95 (upholding concurrent jurisdiction to enforce statutes giving the agencies "cumulative remedies against activity detrimental to competition")). It follows that "[t]o the extent that the agencies choose to divide their workload, such that one brings an action rather than both doing so, this hardly gives a basis for complaint."

Id. (citing *FTC v. AT&T Mobility LLC*, 883 F.3d 848, 862 (9th Cir. 2018) (having "two cops on the beat is nothing unusual")). Any differences in adjudicatory procedures or their outcomes therefore cannot give rise to any constitutional defects, as Respondents would be subject to the procedures applicable to an FTC action regardless of whether the DOJ brought its own action against them in parallel.

Moreover, like the respondents in *Otto Bock*, Respondents here fail to explain how they have purportedly "been prejudiced by any differences in procedures" as between "federal court litigation versus the administrative litigation process." 2019 WL 5957363, at *50. Any differences in procedures between Part 3 adjudication and federal district court litigation are inconsequential, especially since many of the Part 3 rules are modeled from the Federal Rules. As for appeals, legal conclusions by either the Commission or by a federal district court are reviewed *de novo* by the courts of appeal, and any difference between the standards for reviewing factual findings "is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome." *Dickinson v. Zurko*, 527 U.S. 150, 163 (1999). The most notable difference between appeals from federal district court decisions and Part 3 adjudicatory decisions cuts in Respondents' favor; that is, their ability to select which court of appeal will hear their appeal from an adverse decision. Respondents' claim that differences in adjudicatory procedures "can be outcome determinative," Resp. Post-Tr. Br. at 243, does not withstand scrutiny.

Even if there were any outcome-determinative differences between federal court litigation and FTC administrative adjudication, they would not amount to denial of equal protection. Respondents must show not only that the allocation of matters between DOJ and the

FTC makes "classifications" that lead to disparate treatment, but also that the allocation arrangement lacks a "rational relationship to a legitimate governmental purpose." *Tennessee v. Lane*, 541 U.S. 509, 522 (2004). Here, the agencies' allocation arrangement serves the legitimate purpose of "[c]onserving government resources" by avoiding duplicative efforts between agencies with concurrent jurisdiction and enabling each agency to develop unique and industry-specific expertise. *Holt v. Howard*, 806 F.3d 1129, 1133 (8th Cir. 2015); *see also Giarratano v. Johnson*, 521 F.3d 298, 304 (4th Cir. 2008). Rational basis review is satisfied, foreclosing Respondents' equal-protection challenge. *See Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 272 (1979) ("When the basic classification is rationally based, uneven effects upon particular groups within a class are ordinarily of no constitutional concern."). For these reasons, the Proposed Conclusion should be disregarded.

133. No one can seriously dispute that the parties to a merger challenged by the FTC are treated very differently from the parties to a merger challenged by DOJ.

Response to Proposed Conclusion No. 133

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

134. There is no rational basis for these differences, which can be outcome determinative. Treating parties differently based on whether their merger is reviewed by the FTC instead of DOJ is unrelated to any legitimate governmental purpose.

Response to Proposed Conclusion No. 134

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it

should be disregarded.

VII. COMPLAINT COUNSEL'S CASE RUNS COUNTER TO THE OVERWHELMING PROOF AND RESTS ON "EVIDENCE" THAT IS INADMISSIBLE AND/OR DESERVING OF NO WEIGHT

A. Complaint Counsel's Alleged Experts

1. Dr. Fiona Scott Morton

135. Dr. Scott Morton's opinions on MCED technology, the viability of alternative NGS platforms, regulatory approval, and reimbursement should be disregarded because she lacks the scientific expertise to opine on these matters. It is black letter law that experts must be qualified to offer the opinions that they seek to express. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993); *Nat'l Comm'ns. Ass'n v. AT&T*, 1998 WL 118174, at *42–49 (S.D.N.Y. Mar. 16, 1998) (excluding an economic expert's testimony because he conceded he was not an expert in the technical area where he was offering an opinion).

Response to Proposed Conclusion No. 135

Complaint Counsel objects to the Proposed Conclusion because it is misleading and incomplete.

The Proposed Conclusion is misleading and incomplete because it misrepresents the opinions expressed by Dr. Scott Morton and fails to mention that at no time has Dr. Scott Morton represented that she is serving as a scientific, regulatory, or reimbursement expert. This Court has consistently relied on Daubert to assess the admissibility of expert testimony. See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993); *see also* Order Denying Motions In Limine To Exclude Proffered Experts, *In re LabMD, Inc.*, Docket No. 9357, at 2 (May 5, 2014); Order Denying Motions In Limine To Preclude Admission of Expert Opinions And Testimony, *In re McWane Inc.*, Docket No. 9351, at 4 (Aug. 16, 2012). Under *Daubert*, "courts consider whether the expert is qualified in the relevant field and examine the methodology the expert used in reaching the conclusions at issue." *Id.* at 4. Here, [redacted]

[redacted]

Further, the methodology used by Dr. Scott Morton to analyze this transaction is routinely used by economists performing similar analyses. (PX7138 (Scott Morton Trial Dep. at 17).

Following Respondents' logic, the only experts qualified to opine on this merger would require expertise both in the field of economics and also the scientific fields of NGS and MCED. Dr. Scott Morton's expertise as an industrial organization economist is undisputed, and at no time did Dr. Scott Morton represent that she is serving as a scientific, regulatory, or reimbursement expert. (PX7138 (Scott Morton Trial Dep. at 16-17)); (RX3852 (Scott Morton Dep at 22-23)). Despite Dr. Scott Morton's credentials, Respondents assert that Dr. Scott Morton is incapable of analyzing the factual record in formulating her expert opinion because she does not have expertise relating to NGS and MCED technology that even their own economic experts lack. *See, e.g.*, (PX7132 (Willig (Illumina) Dep. at 156)); (RX3871 (Willig Report) ¶ 6); [redacted]. To the extent that Respondents take issue with the materials that Dr. Scott Morton relied upon in formulating her expert opinion, this Court's prior rulings make clear that this goes to the weight and credibility, and not the admissibility, of her testimony. For these reasons, the Court should disregard the Proposed Conclusion.

136. Dr. Scott Morton lacks any scientific expertise to compare and contrast the features of the Galleri test with other MCED tests in development and lacks the clinical expertise to dispute whether or not it would be improper for a physician to use Galleri as a substitute for another test. (PX7138 (Scott Morton, Trial Dep. at 111–12, 177).) *See In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 758 (N.D. Ohio 2014) ("The Court will not permit Bresnahan (or any other economist/damages expert) to offer any opinion suggesting a washer does not have a design defect or has a 'superior design' or is 'innovative.' Bresnahan is not an engineer and has no expertise to render such a conclusion."); *Nat'l Communs. Ass'n*, 1998 WL 118174, at *42–49 (excluding an economic expert's testimony because he conceded he was not an expert in the technical area where he was offering an opinion).

Response to Proposed Conclusion No. 136

Complaint Counsel objects to the Proposed Conclusion because it is incomplete and

misleading.

Respondents improperly analogize certain caselaw. Respondents cite to *In re Whirlpool Corp.*, where plaintiffs sought to exclude portions of an expert's testimony because they alleged the "marketing data and observations" of the testifying economic expert were "beyond his expertise." *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 756-57 (N.D. Ohio 2014). The court held that the economic expert's opinion did not exceed his expertise because he "support[ed] all of his comments on these topics by direct citations to the record or to various third-party literature sources." *In re Whirlpool*, 45 F. Supp. 3d at 756. While the court did exclude portions of the expert's testimony that relied on third-party market research from *Consumer Reports*, it did so because these opinions were "not based on information or data normally relied upon by economists in forming conclusions." *In re Whirlpool*, 45 F. Supp. 3d at 757 (noting that the "majority of the Plaintiff's challenges to [the economic expert's] assumptions go to weight, not admissibility").

Similar to the expert testimony admitted in *Whirlpool*, [redacted] Dr. Scott Morton did not opine on particular technical characteristics of these products, but instead made reasonable assumptions based on the factual record in order to evaluate, *inter alia*, the market structure, the likelihood of NGS entry, and the likely competitive effects of the Proposed Acquisition. *See AT&T*, 310 F. Supp. 3d at 221; *see also See In re Urethane Antitrust Litig.,* 152 F. Supp. 3d 357, 361 (D.N.J. 2016); *In re Processed Egg Products Antitrust Litig.*, 81 F. Supp. 3d 412, 418-25 (E.D. Pa. 2015).

Likewise, Respondents improperly analogize to *National Communications Association* (*"NCA*"), where the court limited expert testimony on a particular technical issue because the expert himself conceded that it was outside of his expertise. *Nat'l Communs. Ass'n v. AT&T*, 1998 WL 118174, at *42–48 (S.D.N.Y. Mar. 16, 1998). By contrast, Dr. Scott Morton did not offer an opinion on particular technical characteristics of these products, but instead made reasonable assumptions based on the factual record in order to evaluate, *inter alia*, the market structure, the likelihood of NGS entry, and the likely competitive effects of the Proposed Acquisition. *See AT&T*, 310 F. Supp. 3d at 221; *see also In re Urethane*; *In re Processed Egg Products*.

Following Respondents' logic, the only experts qualified to opine on this merger would require expertise both in the field of economics and also the scientific fields of NGS and MCED. Dr. Scott Morton's expertise as an industrial organization economist is undisputed, and at no time did Dr. Scott Morton represent that she was serving as a scientific, regulatory, or reimbursement expert. (PX7138 (Scott Morton Trial Dep. at 16-17)); (RX3852 (Scott Morton Dep at 22-23)). Despite Dr. Scott Morton's credentials, Respondents assert that Dr. Scott Morton was incapable of analyzing the factual record in formulating her expert opinion because she does not have expertise relating to NGS and MCED technology that even their own economic experts lack. *See, e.g.*, (PX7132 Willig (Illumina) Dep. at 156); (RX3871 (Willig Report) ¶ 6); [redacted]. To the extent that Respondents take issue with the materials that Dr. Scott Morton relied upon in formulating her expert opinion, this Court's prior rulings make clear that this goes to the weight and credibility, and not the admissibility, of her testimony. For these reasons, the Proposed Conclusion should be disregarded.

137. Dr. Scott Morton did not attempt to fill the information gaps using surveys or other means, including information about the preferences and switching behavior of clinicians, patients, and payors related to the products she includes and excludes from her proposed MCED market, and, most importantly, she did not attempt to analyze substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. These are fatal omissions. *See Teradata Corp. v. SAP SE*, 2021 WL 5178828, at *18 (N.D. Cal. Nov. 8, 2021) ("Asker's methodology in defining the tying market is unreliable. Contrary to Teradata's assertion, he does not measure the cross-elasticity of demand or the substitutability of products based on reliable quantitative and qualitative analyses. Because his methodology for defining the relevant tying market is unreliable, his conclusions that SAP has market power in his proposed market should also be excluded."); *Lantec, Inc. v. Novell, Inc.*, 2001 U.S. Dist. LEXIS 24816, at *14–16 (D. Utah Feb. 13, 2001) ("This is simply insufficient foundation for, or evidence of, the consumer behavior or preferences helpful in defining a relevant market for antitrust purposes. . . . Dr. Beyer's evidence amounts to nothing but anecdotal information from his own experience, that of two IT managers similarly situated, and the experience of one supplier (Lantec) which Dr. Beyer is extrapolating into 'expert evidence.' Lantec has defined the market as 'worldwide,' and the anecdotal evidence cited is statistically insignificant in terms of number and geographic sampling. . . . His conclusions as to the switching costs and therefore the assumed 'lock-in' phenomenon are based on basically the same, and therefore similarly insufficient, foundation.") (citations omitted).

Response to Proposed Conclusion No. 137

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Complaint Counsel objects to the proposed conclusion because it is misleading, incomplete, and misstates the law. "Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one. This is because [t]he market, as most concepts in law or economics cannot be measured by metes and bounds." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 193 (D.D.C. 2017) (internal citations omitted). Contrary to Respondents' assertions, an economic expert's opinion does not need to be based on quantitative information to be probative. *See, e.g., Phila. Nat'l Bank*, 374 U.S. at 362; *H&R Block*, 833 F. Supp. 2d at 88 (finding that an expert's opinion (even when limited by lack of data) can be

helpful to corroborate other evidence in the record like "documents, testimony, and other evidence"); *Aetna*, 240 F. Supp. 3d at 47 (finding that Plaintiff's expert supported the predicted harm that "the merged firm would have the incentive and ability to increase [prices]"); *Sysco*, 113 F. Supp. 3d at 37. Moreover, requiring such a heightened standard would effectively create a safe harbor from antitrust enforcement for companies in industries where pricing data is unavailable in contravention of the plain language of the Clayton Act. 15 U.S.C. § 18. [redacted] Indeed, Respondents cite no case that requires plaintiffs to conduct a "quantitative SSNIP" test or otherwise to analyze price changes or survey data.

[redacted] Dr. Scott Morton's analysis is consistent with well-recognized principles of practical economic analysis, which acknowledge qualitative evidence can be used to estimate diversion. *See* Elizabeth Xia-Ru Wang, *Economic Tools for Evaluating Competitive Harm in Horizontal Mergers*, Practical Law Company at 3 (2013) ("Qualitative industry evidence. This type of evidence, which includes company documents generated during the normal course of business, sometimes provides direct evidence of diversion ratio. For example, company marketing plans

and meeting notes often identify the biggest rival, describe the biggest threat to the company's business or summarize lost sales. Although the qualitative evidence does not provide the exact magnitude of the diversion ratio, the ranking of competitors offers useful rough estimation of that ratio."). For the reasons stated above, the proposed conclusion should be disregarded.

138. Dr. Scott Morton ignored or discounted the evidence of investment, development, and market entry of these companies as well as other companies that are developing non-NGS platforms. *See, e.g.*, *Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Ca. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted."); *Rimbert v. Eli Lilly & Co.*, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009); *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").s

Response to Proposed Conclusion No. 138

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Complaint Counsel objects to the Proposed Conclusion because it misrepresents Dr. Scott Morton's analysis, misstates the law, and is misleading. Respondents make a theoretical assertion that MCED test investment proves NGS entry will occur. *See* Resp. Post-Tr. Br. at 128-29. Their theory is unsupported by fact. Respondents declined to ask a single MCED witness at trial to explain their understanding of the reasons that investors continue to invest in a technology dependent on Illumina. They also failed to put forward any investors in MCED tests at trial to explain whether their investment rationale considered MCED test developers' reliance on Illumina. Without that context, it is inappropriate to draw inferences from MCED test investment because a multitude of factors unrelated to NGS entry can explain the level of

investment. [redacted] For example, Singlera offers a colorectal cancer screening test in China and plans to launch it in the United States in 2022. It is also developing a companion diagnostic test for lung cancer. Likewise, [redacted]

To the contrary, MCED test developers expressed concern regarding the Acquisition's effect on their ability to attract continued investment. (CCFF ¶ 2255); (PX7042 (Gao (Singlera) IHT at 130) (Singlera's investors expressed concern that it is "at the mercy of" Illumina—which "has no incentive to faithfully negotiate with anyone" now that it is "getting into the [MCED testing] field"—and therefore Singlera will have more difficulty attracting future investment.)); *see also* (CCFF ¶ 3606) (Helio's Chahine warning that investors could see MCED testing as a "foregone conclusion" post-Acquisition, allowing "investment [to] [dr[y] up . . . [which] could have negative consequences for innovation"). For the reasons stated above, the Proposed

Conclusion should be disregarded.

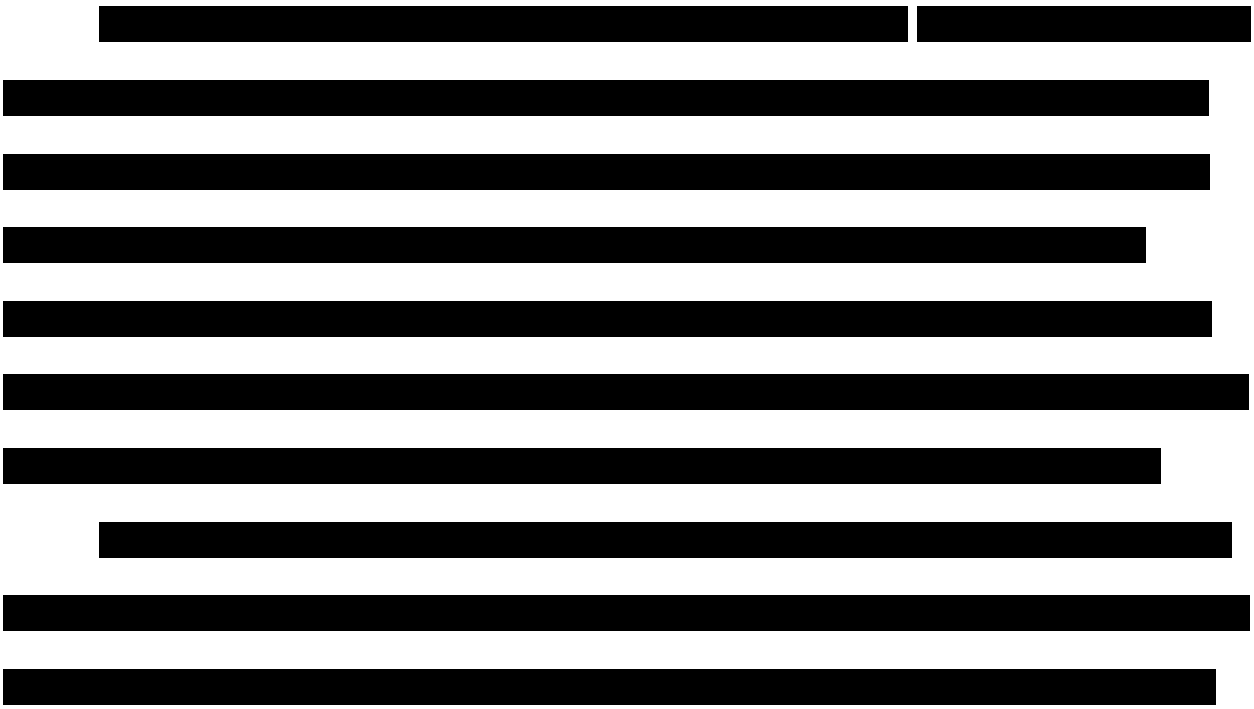
139. Dr. Scott Morton's conclusion that Illumina allegedly will foreclose competition in the alleged MCED market by raising rivals' costs is based entirely on speculation. Dr. Scott Morton did not analyze the degree to which Illumina would have to raise the prices to GRAIL's putative rivals to effectively foreclose them. (Scott Morton, Tr. 224.) Dr. Scott Morton's "model" does not account for any efficiencies, ignoring the statement in the Vertical Guidelines that vertical mergers have the capacity to generate cognizable efficiencies. (Vertical Merger Guidelines, at 11). And Dr. Scott Morton does not perform a diversion analysis and disregards the testimony of Respondents' two experts who are practicing physicians, Drs. Cote and Abrams, who have testified that number of cancers detected and signal of origin are key differentiating features that will affect physician and patient choice. (Abrams, Tr. 3624; [redacted] Given these flaws, Dr. Scott Morton's foreclosure analysis is unreliable. *See Teradata Corp.*, 2021 WL 5178828, at *18.

Response to Proposed Conclusion No. 139

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Complaint Counsel objects to the Proposed Conclusion because it misrepresents Dr. Scott Morton's analysis, misstates the law, and is misleading. [redacted] Dr. Scott Morton's analysis is consistent with well-recognized principles of practical economic analysis, which acknowledge qualitative evidence can be used to estimate diversion. *See* Elizabeth Xia-Ru Wang, *Economic Tools for Evaluating Competitive Harm in Horizontal Mergers*, Practical Law Company at 3 (2013) ("Qualitative industry evidence. This type of evidence, which includes company documents generated during the normal course of business, sometimes provides direct evidence of diversion ratio. For example, company marketing plans

and meeting notes often identify the biggest rival, describe the biggest threat to the company's business or summarize lost sales. Although the qualitative evidence does not provide the exact magnitude of the diversion ratio, the ranking of competitors offers useful rough estimation of that ratio."). Next, Respondents argue that Complaint Counsel's case fails because it did not estimate the amount of Grail's rivals' sales that would be diverted to Grail. Resp. Post-Tr. Br. at 97 (arguing that Complaint Counsel cannot show diversion because "there are no sales to divert" and therefore Illumina "would just lose sales"). Respondents once again seek to create a hyper-technical standard that would essentially eliminate enforcement in dynamic industries. *See* CC Post-Tr. Repl. Br. § I.B.1.a. Finally, Respondents imply that Illumina would not have the incentive to disadvantage Grail's rivals unless it could increase sales *to* Grail *from* other MCED test developers. In making their diversion argument, Respondents ignore that Illumina will nonetheless have the incentive to protect Grail from its rivals who aim to cannibalize its sales. *See* (CCFF ¶¶ 3079-3569).



[redacted] Indeed, her conclusion is consistent with [redacted]. Ultimately, it is Respondents' burden to establish the likelihood and magnitude of their claimed efficiencies, *Otto Bock*, 2019 WL 2118886, at *49-50 (Chappell, A.L.J.), which Respondents have failed to demonstrate in the face of record evidence suggesting that the merger is unlikely to result in any of their claimed efficiencies. For the reasons stated above, the Proposed Conclusion should be disregarded.

140. Dr. Scott Morton's opinions are inadmissible and unreliable to the extent that she impermissibly usurps the role of the fact finder by opining on the credibility of witness testimony or weighing the evidence. "The credibility of witness testimony is a matter left to the [fact finder] and generally is not an appropriate subject for expert testimony." *Wilson v. Muckala*, 303 F.3d 1207, 1218 (10th Cir. 2002); *see also United States v. Adams*, 271 F.3d 1236, 1246 (10th Cir. 2001) ("The offered testimony does little more than vouch for the credibility of another witness and thereby encroaches upon the [fact finder's] vital and exclusive function to make credibility determinations." (internal quotations omitted)).

Response to Proposed Conclusion No. 140

Complaint Counsel objects to the Proposed Conclusion because it is misleading and misstates the law. Dr. Scott Morton's review of the factual record is critical for her conclusions to rest upon "assumptions that are reasonable in light on the record evidence" in order to evaluate the relevant markets. *AT&T*, 310 F. Supp. 3d at 221. To the extent Respondents believe Dr. Scott Morton's conclusions improperly rest upon third-party testimony over Respondents' executives' testimony, this speaks to weight, not the admissibility of her opinions. For the reasons stated above, the Proposed Conclusion should be disregarded.

2. **Dr. Amol Navathe**

141. Courts routinely disregard expert opinions regarding FDA regulations where the expert's only connection to the FDA is through his experience as a physician. *See, e.g.*, *Hall v. Boston Scientific Corp.*, 2015 WL 868907, at *24 (S.D.W.V. Feb. 27, 2015) (finding that expert's "distinguished career as a urogynecologist cannot uphold his opinions on product warnings and FDA compliance.")

Response to Proposed Conclusion No. 141

Complaint Counsel objects to the Proposed Conclusion because it is incomplete and misleading. *Hall* addresses the question of qualification when the expert's only connection to the FDA is through the expert's experience as a physician. *Hall v. Boston Scientific Corp.*, 2015 WL 868907, at *24 (S.D.W.V. Feb. 27, 2015). That is clearly not the case here, where Dr. Navathe is a teaching and researching academic who has performed research relating to FDA approvals for medical diagnostics. (PX7139 (Navathe Trial Dep. at 7-13). For the reasons stated above, the Proposed Conclusion should be disregarded.

142. Allowing "experts" to testify as to purely subjective views in the guise of expert opinions would "border on the absurd." *In re Rezulin Products Liability Litig.*, 309 F. Supp. 2d 531, 544 (S.D.N.Y. 2004).

Response to Proposed Conclusion No. 142

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Complaint Counsel objects to the Proposed Conclusion because it is incomplete and misleading. The experts excluded by the court in *In re Rezulin* disclaimed knowledge of the FDA process and characterized some of their own opinions as "'personal,' rather than 'scientific,'" or "based on an 'impression' or a 'bet.'" *In re Rezulin Products Liability Litigation*, 309 F. Supp. 2d 531, 549 & n.56 (S.D.N.Y. 2004). In contrast, Dr. Navathe has relevant,

demonstrable, specialized knowledge and expertise. *See generally* (PX7139 (Navathe Trial Dep. at 7-19). In his report, Dr. Navathe relied on his knowledge and expertise to, for example,

[redacted]

143. Having merely reviewed selected documents provided to him by Complaint Counsel, Dr. Navathe cannot properly testify regarding acceleration. *See Mid-State Fertilizer Co. v. Exch. Nat'l Bank*, 877 F.2d 1333, 1340 (7th Cir. 1989) (excluding economist who merely "examined materials produced in discovery and drew inferences from the record" instead of "draw[ing] on the skills of an economist").

Response to Proposed Conclusion No. 143

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law.

Respondents misapprehend the purpose of Dr. Navathe's analysis. Dr. Navathe is a rebuttal expert. A rebuttal expert may critique another's theories or conclusions, and "need not offer his own independent theories or conclusions." *In re Cessna 208 Series Aircraft Prod. Liab. Litig.*, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009); *see also, e.g.*, *Pandora Jewelers 1995, Inc. v. Pandora Jewelry, LLC*, 2011 WL 2295269, at *5 (S.D. Fla. June 8, 2011) ("A rebuttal expert can testify as to the flaws that she believed are inherent in another expert's report that implicitly assumes or ignores certain facts."). That Dr. Navathe does not [redacted] is not a basis for exclusion of his opinions.

In forming his opinions, Dr. Navathe did not merely "examine[] materials produced in

discovery and dr[a]w inferences from the record," as Respondents contend. Rather, he relied on his own expertise, both as a teaching and as a researching academic who has performed research relating to FDA approvals for medical diagnostics, (PX7139 (Navathe Trial Dep. at 7-13), to point out the infirmities in [redacted] Dr. Deverka's opinions. In his report, Dr. Navathe relied on his knowledge and expertise to, for example [redacted]

For the reasons stated above, the Proposed Conclusion should be disregarded.

144. Dr. Navathe's critique usurps the role of the Court insofar as he purports to opine on whether Respondents made a sufficient showing of an efficiency. *See Mid-State Fertilizer Co.*, 877 F.2d at 1340 (excluding economist who merely "examined materials produced in discovery and drew inferences from the record" instead of "draw[ing] on the skills of an economist"); *SEC v. Tourre*, 950 F. Supp. 2d 666, 675, 678, 681-82 (S.D.N.Y. 2013) ("Acting simply as a narrator of the facts does not convey opinions based on an expert's knowledge and expertise; nor is such a narration traceable to a reliable methodology.").

Response to Proposed Conclusion No. 144

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, misstates the law, and relies on cases that cannot possibly be construed to say anything about the ability of a rebuttal expert to critique expert witness testimony about purported efficiencies.

Respondents' cases do not reference, in any conceivable way, anything that supports the proposition that a rebuttal expert cannot critique expert witness testimony about purported

efficiencies. The court in *Toure* excluded the opinion of the defendant's expert, who the court determined was "not qualified to present [his] opinion" because he had "no education, expertise, or experience in this area upon which to [opine]." *SEC. v. Tourre*, 950 F. Supp. 2d 666, 675-78 (S.D.N.Y. 2013). The Court in *Toure* allowed two experts to testify for the SEC but did not allow the experts to opine as to the defendant's guilt or whether the legal element of whether marketing materials were "misleading" had been met. *Toure*, 950 F. Supp. 2d at 681-82. *Mid-State* is similarly irrelevant. The *Mid-State* court excluded the opinion of an expert who "presented nothing but conclusions—no facts, no hint of an inferential process, no discussion of hypotheses considered and rejected," and "offered the court his CV rather than his economic skills." *Mid-State Fertilizer Co. v. Exch. Nat. Bank of Chicago*, 877 F.2d 1333, 1339-40 (7th Cir. 1989). Neither the subject nor the court's rationale bear even the slightest resemblance to the Proposed Conclusion for which Respondents cite them. Accordingly, the Court should disregard this Proposed Conclusion.

Moreover, Respondents misapprehend the purpose of Dr. Navathe's analysis. Dr. Navathe is a rebuttal expert. A rebuttal expert may critique another's theories or conclusions, and "need not offer his own independent theories or conclusions." *In re Cessna 208 Series Aircraft Prod. Liab. Litig.*, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009); *see also, e.g.*, *Pandora Jewelers 1995, Inc. v. Pandora Jewelry, LLC*, 2011 WL 2295269, at *5 (S.D. Fla. June 8, 2011) ("A rebuttal expert can testify as to the flaws that she believed are inherent in another expert's report that implicitly assumes or ignores certain facts."). That Dr. Navathe does not [redacted] is not a basis for exclusion of his opinions.

In forming his opinions, Dr. Navathe did not merely "dr[a]w inferences from the record" or act as a "narrator of the facts," as Respondents contend. Rather, he relied on his own

expertise, both as a teaching and as a researching academic who has performed research relating to FDA approvals for medical diagnostics, (PX7139 (Navathe Trial Dep. at 7-13), to point out the infirmities in [redacted] Dr. Deverka's opinions. In his report, Dr. Navathe relied on his knowledge and expertise to, for example [redacted]

For the reasons stated above, the Proposed Conclusion should be disregarded.

145. Even if Dr. Navathe could appropriately offer such an opinion, he could not do so here because he failed even to assess the entirety of the proof put forward by Respondents. *See, e.g.*, *Abarca*, 761 F. Supp. 2d at 1066 n.60 ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted.").

Response to Proposed Conclusion No. 145

Complaint Counsel objects to the Proposed Conclusion because it is misleading, incomplete, and misstates the law. The Proposed Conclusion is also vague in that it's unclear what proof Dr. Navathe should have allegedly reviewed.

Respondents misapprehend the purpose of Dr. Navathe's analysis. Dr. Navathe is a rebuttal expert. "A rebuttal expert can testify as to the flaws that she believed are inherent in another expert's report that implicitly assumes or ignores certain facts." *Pandora Jewelers 1995, Inc. v. Pandora Jewelry, LLC*, 2011 WL 2295269, at *5 (S.D. Fla. June 8, 2011); *see also, e.g.*,

In re Cessna 208 Series Aircraft Prod. Liab. Litig., No. 05-MD-1721-KHV, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009) ("need not offer his own independent theories or conclusions"). A rebuttal expert may critique another's theories or conclusions and does not need to "assess the entirety of the proof put forward by Respondents." For the reasons stated above, the Proposed Conclusion should be disregarded.

3. **Dr. Dov Rothman**

146. Like Dr. Navathe's critique of Dr. Carlton, these opinions should be given no weight because they invade the Court's province and constitute improper legal opinion. *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d at 64 ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law.").

Response to Proposed Conclusion No. 146

Complaint Counsel objects to the Proposed Conclusion because it is incomplete, misleading, and misstates the law.

Although courts routinely apply the Horizontal Merger Guidelines and find them to be a useful description of legal and economic tools available to evaluate mergers, *see, e.g.*, *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 38–39 (D.D.C 2015), "[i]t is well-recognized that the Merger Guidelines do not have the force of law." *Community Publishers, Inc. v. Donrey Corp.*, 892 F. Supp. 1146, 1153 n.6 (W.D. Ark. 1995) (noting that "the expert testimony in this case shows that [the Horizontal Merger Guidelines] represent mainstream economic thinking") (internal citations omitted). Rather, "the Merger Guidelines are an excellent summary of a very broad set of tools that are used by economists to engage in antitrust analysis." *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 206 (D.D.C. 2018) (quotation marks and citation omitted); *see also* Joseph Farrell & Carl Shapiro, *The 2010 Horizontal Merger Guidelines After 10 Years*, 58 Rev. Indus. Org. 1) ("Since the first Merger Guidelines were issued by the DOJ 1968, the merger guidelines have been an important channel by which economic research and learning affects antitrust enforcement. Each

iteration of the merger guidelines has reflected the economic thinking of the day."). Notably, the Horizontal Merger Guidelines are drafted by both economists and attorneys from the Department of Justice and the Federal Trade Commission and set forth an analytical framework that represents both an economic and legal consensus regarding merger analysis. *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 206 (D.D.C. 2018).

Respondents' sole support for the Proposed Conclusion is an inapposite case. *In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61 (S.D.N.Y. 2001) ("*In re IPO"*). In *In re IPO*, the court denied admission to declarations and an affidavit from two law professors. 174 F. Supp. 2d at 63-64. The first professor submitted a declaration that stated that he had been asked by the party moving for admission to "give [his] opinion concerning whether 28 U.S.C. § 455 requires recusal of the presiding district court judge." *In re IPO*, 174 F. Supp. 2d at 63. The second professor submitted a letter seeking permission to file, *inter alia*, a "thirty-five page memorandum of law." *In re IPO*, 174 F. Supp. 2d at 63. *In re IPO* is easily distinguished from the case at hand, as Dr. Rothman has done nothing that even resembles the blatant offering of legal conclusions of the *In re IPO* professors.

At no point does Dr. Rothman "invade the court's province by testifying on issues of law." Dr. Rothman neither interprets the Merger Guidelines nor reaches any legal conclusion. As he clearly explains in his report, he [redacted] This is the standard approach used by economic experts in countless merger cases to analyze not only efficiencies, but other issues such as market definition. In fact, Respondents' own expert used the Merger Guidelines in much the same way. [redacted]

[redacted] For the reasons stated above, the Proposed Conclusion should be disregarded.

147. To the extent that Dr. Rothman intends his interpretations of the Guidelines to guide the ALJ's assessment of what may constitute a cognizable efficiency, his opinions improperly invade the Court's province. *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d at 64.

Response to Proposed Conclusion No. 147

Complaint Counsel objects to the Proposed Conclusion because it is incomplete, misleading, and misstates the law.

Although courts routinely apply the Merger Guidelines and find them to be a useful description of legal and economic tools available to evaluate mergers, *see, e.g., FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 38–39 (D.D.C 2015), "[i]t is well-recognized that the Merger Guidelines do not have the force of law." *Community Publishers, Inc. v. Donrey Corp.*, 892 F. Supp. 1146, 1153 n.6 (W.D. Ark. 1995) (noting that "the expert testimony in this case shows that [the Merger Guidelines] represent mainstream economic thinking") (internal citations omitted). Rather, "the Merger Guidelines are an excellent summary of a very broad set of tools that are used by economists to engage in antitrust analysis." *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 206 (D.D.C. 2018) (quotation marks and citation omitted); *see also* Joseph Farrell & Carl Shapiro, *The 2010 Horizontal Merger Guidelines After 10 Years*, 58 Rev. Indus. Org. 1) ("Since the first Merger Guidelines were issued by the DOJ 1968, the merger guidelines have been an important channel by which economic research and learning affects antitrust enforcement. Each

iteration of the merger guidelines has reflected the economic thinking of the day."). Notably, the Merger Guidelines are drafted by both economists and attorneys from the Department of Justice and the Federal Trade Commission and set forth an analytical framework that represents both an economic and legal consensus regarding merger analysis. *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 206 (D.D.C. 2018).

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At no point does Dr. Rothman "invade the court's province by testifying on issues of law." Dr. Rothman neither interprets the Merger Guidelines nor reaches any legal conclusion. As he clearly explains in his report, he [redacted] This is the standard approach used by economic experts in countless merger cases to analyze not only efficiencies, but other issues such as market definition. In fact, Respondents' own expert used the Merger Guidelines in much the same way. [redacted]

[redacted] For the reasons stated above, the Proposed Conclusion should be disregarded.

148. Dr. Rothman's artificially limited inquiry to only materials he characterizes as specifically "offered as substantiation," makes his opinions irrelevant and unreliable. *See In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d at 425, 437-38 (excluding experts that "ignored a large amount of information").

Response to Proposed Conclusion No. 148

Complaint Counsel objects to the Proposed Conclusion because it is incomplete, misleading, and misstates the law.

In considering the admissibility of expert testimony, one factor that courts have considered is "whether an expert has accounted adequately for obvious alternative explanations." *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 420 (S.D.N.Y. 2005). Respondents do not argue that Dr. Rothman failed to account for "obvious alternative explanations." Instead, Respondents object that "Dr. Rothman did not conduct a study of record evidence to determine whether support for any efficiency existed and he did not analyze all of the evidence considered in Respondents' expert reports." Resp. Post-Tr. Br. at 269-70. This is utterly distinct from the sole case that Respondents cite as their authority for the Proposed Conclusion.

The facts of *In re Rezulin* are wholly inapplicable to this case. The *In re Rezulin* court excluded testimony by experts who offered opinions that Rezulin could cause apoptosis, but whose "reports [did] not mention that the one study that looked for Rezulin-induced apoptosis in humans failed to find it." *In re Rezulin,* 369 F.Supp.2d at 425. By contrast, Dr. Rothman

responded to the claims and alleged substantiation offered by Respondents' experts and opined as to whether Respondents' experts showed cognizable efficiencies. [redacted] Dr. Rothman's [redacted] stands in stark contrast to the experts in *In re Rezulin*, who failed to consider the only publication on the subject on which they were to opine. *In re Rezuliny,* 369 F.Supp.2d at 425. For the reasons stated above, the Proposed Conclusion should be disregarded.

B. IH Transcripts and Other Documents

149. The IH testimony of third parties was wasteful and cumulative in light of the fact that the court also admitted deposition testimony and trial testimony, and vastly expanded Complaint Counsel's effective trial time. *See In re McWane*, No. 9351, 2012 WL 3597376 (FTC Aug. 15, 2012).

Response to Proposed Conclusion No. 149

Complaint Counsel objects to the Proposed Conclusion because it is incomplete, misleading, and misstates the law.

Rule 3.43(b) requires admission of all evidence that is "relevant, material, and reliable," unless that evidence is more prejudicial than probative, or its presentation would cause "undue delay, waste of time, or needless presentation of cumulative evidence." 16 C.F.R. § 3.43(b). Significantly, the Commission amended Rule 3.43(b) in 2009 to add language that expressly allows for the admission of IH transcripts:

> "If otherwise meeting the standards for admissibility described in this paragraph, depositions, ***investigational hearings***, prior testimony in Commission or other proceedings, expert reports, and any other form of hearsay, shall be admissible and shall not be excluded solely on the ground that they are or contain hearsay."

74 Fed. Reg. 1804-01, 1831 (Jan. 13, 2009) (emphasis added). In addition, Rule 3.43(b) requires admission of all relevant party-opponent statements. 16 C.F.R. § 3.43(b) ("Statements

or testimony by a party-opponent, if relevant, *shall* be admitted.") (emphasis added).

As this Court explained, IHTs are not automatically admissible. *In re McWane*, No. 9351, 2012 WL 3597376, at *4 (FTC Aug. 15, 2012). Rather, "Rule 3.43 clearly contemplates that individual portions of investigational hearing testimony can be excluded, like any other proffered evidence, if the testimony is irrelevant, unreliable, duplicative, or otherwise fails to '"meet[ ] the standards for admissibility described in' Rule 3.43. 16 C.F.R. § 3.43(b)." *In re McWane*, 2012 WL 3597376, at *4.

The Proposed Conclusion is nearly identical to the arguments that this Court rejected from the respondents in *McWane*—a general assertion that all third party IHTs are "a 'waste of time' and 'needless presentation of cumulative evidence' [because] Complaint Counsel also has taken the deposition of every witness who provided testimony earlier at an investigational hearing." *McWane*, 2012 WL 3597376, at *2. This Court rightly rejected that argument, as the *McWane* respondents "failed to identify any testimony that has been designated by Complaint Counsel to which it objects, and Respondent's general assertions of unreliability or duplication of evidence are insufficient." *In re McWane*, 2012 WL 3597376, at *4. Respondents here make the same defective argument, and both fail to identify any specific testimony to which they object, and only make a general assertion that the IHTs are wasteful and cumulative. Moreover, Respondents themselves cited IH testimony dozens of time in their proposed findings of facts despite their arguments to this court. For the reasons stated above, the Proposed Conclusion should be disregarded.

150. Furthermore, IH testimony constitutes inadmissible hearsay because: (1) it is not necessary to "aid in the determination of the matter" as Complaint Counsel could and did take deposition testimony from most of the nonparties represented in the IHTs; and (2) the IHTs are not "reliable" or "fair", as they are replete with improper leading questions, speculation and inadmissible lay opinion. *See In re Resort Car Rental Sys., Inc.*, 83 FTC 234, 1973 WL 165056, at *33 (July 31, 1973) ("Complaint counsel made a request . . . to introduce into evidence

excerpts of testimony attained at an investigational hearing, for the truth of the matters contained therein. The administrative law judge rejected this evidence . . . .").

Response to Proposed Conclusion No. 150

Complaint Counsel objects to the Proposed Conclusion because it misstates the law. Respondents sole support for the Proposed Conclusion is a case that was superseded by the Commission's amendment of Rule 3.43(b) in 2009. *In re Resort Car Rental Sys., Inc.*, 83 FTC 234, 1973 WL 165056 (July 31, 1973), *superseded by* 74 Fed. Reg. 1804-01, 1831 (Jan. 13, 2009).

Rule 3.43(b) requires admission of all evidence that is "relevant, material, and reliable," unless that evidence is more prejudicial than probative, or its presentation would cause "undue delay, waste of time, or needless presentation of cumulative evidence." 16 C.F.R. § 3.43(b). Significantly, the Commission amended Rule 3.43(b) in 2009 to add language that expressly allows for the admission of IH transcripts:

> "If otherwise meeting the standards for admissibility described in this paragraph, depositions, ***investigational hearings***, prior testimony in Commission or other proceedings, expert reports, and any other form of hearsay, shall be admissible and shall not be excluded solely on the ground that they are or contain hearsay."

74 Fed. Reg. 1804-01, 1831 (Jan. 13, 2009) (emphasis added). In addition, Rule 3.43(b) requires admission of all relevant party-opponent statements. 16 C.F.R. § 3.43(b) ("Statements or testimony by a party-opponent, if relevant, *shall* be admitted.") (emphasis added).

As this Court explained, IHTs are not automatically admissible. *In re McWane*, 2012 WL 3597376, at *4 (FTC Aug. 15, 2012). Rather, "Rule 3.43 clearly contemplates that individual portions of investigational hearing testimony can be excluded, like any other proffered evidence, if the testimony is irrelevant, unreliable, duplicative, or otherwise fails to 'meet[ ] the standards for admissibility described in' Rule 3.43. 16 C.F.R. § 3.43(b)." *In re McWane*, 2012 WL 3597376, at *4. But as was explained *supra*, CC Resp. RPFF ¶ 149, Respondents fail to

identify any specific testimony to which they object, and only make a general assertion that the IHTs are wasteful and cumulative. Moreover, Respondents themselves cited IH testimony dozens of time in their proposed findings of facts despite their arguments to this court. For the reasons stated above, the Proposed Conclusion should be disregarded.

VIII. COMPLAINT COUNSEL IS NOT ENTITLED TO THE REMEDY IT SEEKS

151. Complaint Counsel's request for a divestiture is overbroad, against the public interest and inequitable. Accordingly, it should be denied.

Response to Proposed Conclusion No. 151

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is contrary to the law. The "legitimate objective" in a Section 7 case is to "restore the competitive intensity" lost from the Acquisition. *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72). Far from being "punitive" and "overbroad," divestiture of an ongoing business is considered by courts to be the "natural remedy" for a Section 7 violation. *du Pont 1961*, 366 U.S. at 329; *see also Ford*, 405 U.S. at 573 (stating that "[c]omplete divestiture is particularly appropriate where . . . acquisitions violate the antitrust laws"); *RSR Corp. v. FTC*, 602 F.2d 1317, 1326 n.5 (9th Cir. 1979) (stating that "complete divestiture of all pre-merger assets is the usual remedy for a Section 7 violation."). Conduct remedies, in contrast "are inappropriate except in very narrow circumstances." DOJ, Merger Remedies Manual § II (2020); *see also Steves & Sons*, 988 F.3d at 720 (noting that "conduct remedies are disfavored"). Therefore, the Proposed Conclusion should be disregarded.

152. A divestiture remedy would be overbroad and unnecessarily punitive. The purpose of an antitrust remedy is to "restore competition". *United States* v. *E. I. du Pont de*

Nemours & Co., 366 U.S. 316, 326 (1961). "Courts are not authorized in civil proceedings to punish . . . and relief must not be punitive." *Id.* The idea is to "attempt to craft a remedy that will create a competitive environment that would have existed in the absence of the violations." *In re Evanston Nw. Healthcare Corp.*, No. 9315, 2007 WL 2286195, at *77 (F.T.C. Aug. 6, 2007). "Absent some measure of confidence that there has been an actual loss to competition that needs to be restored, wisdom counsels against adopting radical structural relief.'" *New York* v. *Deutsche Telekom AG*, 439 F. Supp. 3d 179, 230 n.23 (S.D.N.Y. 2020) (quoting *United States* v. *Microsoft Corp.*, 253 F.3d 34, 80 (D.C. Cir. 2001)).

Response to Proposed Conclusion No. 152

This Proposed Conclusion is incorrect and contrary to the law for the reasons provided in Complaint Counsel's post-trial briefing. *See* Complaint Counsel's Post-Trial Brief § II.G; Complaint Counsel's Post-Trial Reply Brief § VII. The "legitimate objective" in a Section 7 case is to "restore the competitive intensity" lost from the Acquisition. *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72). Far from being "punitive" and "overbroad," divestiture of an ongoing business is considered by courts to be the "natural remedy" for a Section 7 violation. *du Pont 1961*, 366 U.S. at 329; *see also Ford*, 405 U.S. at 573 (stating that "[c]omplete divestiture is particularly appropriate where . . . acquisitions violate the antitrust laws"); *RSR Corp. v. FTC*, 602 F.2d 1317, 1326 n.5 (9th Cir. 1979) (stating that "complete divestiture of all pre-merger assets is the usual remedy for a Section 7 violation."). Conduct remedies, in contrast "are inappropriate except in very narrow circumstances." DOJ, Merger Remedies Manual § II (2020); *see also Steves & Sons*, 988 F.3d at 720 (noting that "conduct remedies are disfavored"). Therefore, the Proposed Conclusion should be disregarded.

153. A divestiture order would be unnecessarily punitive, eliminating the life-saving benefits of the Transaction in order to address concerns that are entirely eliminated by the Open Offer. Illumina's Open Offer eliminates all of the alleged concerns raised by Complaint Counsel. Illumina has committed to formalize these binding contractual commitments in a consent order. A Commission consent order requiring Illumina to abide by the terms of the Open Offer would be a more appropriate and effective remedy than divestiture. A consent order would allow the combined company to continue pursuing its plan to save more lives, more quickly. *See AT&T,* 916 F.3d at 1041 (noting that the government has recognized, "especially in vertical mergers, that conduct remedies . . . can be a very useful tool to address the competitive

problems while preserving competition and allowing efficiencies that may result from the transaction").

Response to Proposed Conclusion No. 153

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence (aside from a reference to *AT&T* that it does not even cite for a legal conclusion) as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Complaint Counsel does not dispute that MCED tests "are poised to turn the tide in the war on cancer" by "detect[ing] multiple cancers at early stages, leading to improved outcomes and saving lives." Complaint Counsel's Post-Trial Brief at 1. However, Respondents have not demonstrated the Acquisition will accelerate the adoption of Galleri, and therefore, Respondents have failed to show their Acquisition would save any lives. *See* Complaint Counsel's Post-Trial Reply Brief § V.A-B. Therefore, the Proposed Conclusion should be disregarded.

Respondents' Proposed Conclusion that the "divestiture order would be unnecessarily punitive" is not a conclusion of law and is unsupported, incorrect, and contrary to the law for the reasons described in Response to Proposed Conclusion No. 152.

Respondents' Proposed Conclusion that "Illumina has committed to formalize these binding contractual commitments in a consent order" is not a conclusion of law and is unsupported, inaccurate, and misleading for the reasons described in Response to Proposed Conclusion No. 92.

The rest of Respondents' Proposed Conclusion is misleading and contrary to the weight of the evidence to the extent it implies that Respondents' purported (and unsubstantiated) efficiencies' claims mean that a behavioral remedy is more appropriate than a divestiture.

Respondents simply rehash their alleged efficiencies defense to argue that a divestiture of Grail would harm "the interest of the general public." Resp. Post-Tr. Br. at 278 (internal quotations omitted). As explained in Complaint Counsel's post-trial reply brief, *see* Complaint Counsel's Post-Trial Reply Brief § V, and in Complaint Counsel's post-trial brief, *see* Complaint Counsel's Post-Trial Brief § II.G.2. Respondents' alleged efficiencies are wholly inadequate to rebut Complaint Counsel's *prima facie* case and, thus, are also insufficient to avoid the "natural remedy" of a divestiture. *du Pont 1961*, 366 U.S. at 329. Further, in passing the Clayton Act, Congress determined that the public interest is served by competition. *See FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Congress was aware that some mergers which lessen competition may also result in economies but it struck the balance in favor of protecting competition."); *Brown Shoe*, 370 U.S. at 344 (stating that "we cannot fail to recognize Congress' desire to promote competition"). Here, restoring the status quo through a divestiture of Grail's standalone business will both preserve competition in the research, development, and commercialization of MCED tests and, through such competition, will lead to improved cancer screening tests that will save countless lives. Therefore, the Proposed Conclusion should be disregarded.

154. A divestiture of GRAIL would result in harm to "the interest of the general public." *United States* v. *Am. Tobacco Co*., 221 U.S. 106, 185 (1911). Where divestiture will result in the elimination of benefits that have been created by a merger, an alternative remedy is appropriate. In *Evanston*, Complaint Counsel sought the divestiture of respondent's acquisition of Highland Park Hospital and Chief Administrative Law Judge McGuire agreed. The Commission reversed Judge McGuire's divestiture order and instead entered an injunctive remedy. *In the Matter of Evanston Nw. Healthcare Corp.,* No. 9315, 2007 WL 2286195 (F.T.C. Aug. 6, 2007) (requiring respondent to provide a non-divestiture proposal to the Commission for relief that would remedy the alleged harm). In reaching its decision, the Commission noted that respondent had "made improvements at Highland Park since the merger." *In re Evanston*, 2007 WL 2286195, at *78. The improvements were "relevant to determining whether divestiture is appropriate because divestiture may reduce or eliminate the resulting benefits for a material period of time." *Id.*

Response to Proposed Conclusion No. 154

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Consequently, it should be disregarded.

The Proposed Conclusion is misleading, contrary to the law, and contrary to the weight of the evidence to the extent it implies that Respondents' purported (and unsubstantiated) efficiencies' claims mean that a behavioral remedy is more appropriate than a divestiture. Respondents inaccurately and incorrectly cite to *In re Evanston Northwestern Healthcare Corp*. to support their claim. But *Evanston* provides:

> Structural remedies are preferred for Section 7 violations. *See United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 329 (1961) (calling divestiture "a natural remedy" when a merger violates the antitrust laws). As we recently said, "[m]uch of the case law has **. . .** found divestiture the most appropriate means for restoring competition lost as a consequence of a merger or acquisition." *In re Chicago Bridge & Iron Co.*, No. 9300, 2005 WL 120878, at 93 (FTC Jan. 6, 2005). Divestiture is desirable because, in general, a remedy is more likely to restore competition if the firms that engaged in pre-merger competition are not under common ownership. There are also usually greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution.

2007 WL 2286195, at *77 (F.T.C. Aug. 6, 2007). In *Evanston* the court ultimately determined that "this is the *highly unusual case* in which a conduct remedy, rather than divestiture, is more appropriate," but noted that the reasoning will not necessarily "apply to consideration of the appropriate remedy in a future challenge to a consummated merger. Divestiture is the preferred remedy for challenges to unlawful mergers, regardless of whether the challenge occurs before or after consummation." *Id.* at *79 (emphasis added). Particularly, the court noted that "where it is relatively clear that the unwinding . . . would be unlikely to involve substantial costs, all else being equal, the Commission likely would select divestiture as the remedy." *Id.* [redacted]

[redacted]

[redacted]

Moreover, Respondents simply rehash their alleged efficiencies defense to argue that a divestiture of Grail would harm "the interest of the general public." Resp. Post-Tr. Br. at 278 (internal quotations omitted). As explained in Complaint Counsel's post-trial reply brief, *see* Complaint Counsel's Post-Trial Reply Brief § V, and in Complaint Counsel's post-trial brief, *see* Complaint Counsel's Post-Trial Brief § II.G.2., Respondents' alleged efficiencies are wholly inadequate to rebut Complaint Counsel's *prima facie* case and, thus, are also insufficient to avoid the "natural remedy" of a divestiture. *du Pont 1961*, 366 U.S. at 329. Further, in passing the Clayton Act, Congress determined that the public interest is served by competition. *See FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Congress was aware that some mergers which lessen competition may also result in economies but it struck the balance in favor of protecting competition."); *Brown Shoe*, 370 U.S. at 344 (stating that "we cannot fail to recognize Congress' desire to promote competition"). Here, restoring the status quo through a divestiture of Grail's standalone business will both preserve competition in the research, development, and commercialization of MCED tests and, through such competition, will lead to improved cancer screening tests that will save countless lives. Therefore, the Proposed Conclusion should be disregarded.

155. If the Transaction is allowed to proceed, it will result in significant efficiencies, including the saving of thousands of lives, the acceleration of Galleri, significant cost savings and R&D efficiencies. A divestiture would eliminate all of these efficiencies at great loss to the public interest

Response to Proposed Conclusion No. 155

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

Complaint Counsel does not dispute that MCED tests "are poised to turn the tide in the war on cancer" by "detect[ing] multiple cancers at early stages, leading to improved outcomes and saving lives." Complaint Counsel's Post-Trial Brief at 1. However, Respondents have not demonstrated the Acquisition will actually save thousands of lives, accelerate the adoption of Galleri, or result in cost savings or R&D efficiencies. *See* Complaint Counsel's Post-Trial Reply Brief § V.A-B. Therefore, the Proposed Conclusion should be disregarded.

The Proposed Conclusion is misleading and contrary to the weight of the evidence to the extent it implies that Respondents' purported (and unsubstantiated) efficiencies' claims mean that a behavioral remedy is more appropriate than a divestiture. Respondents simply rehash their alleged efficiencies defense to argue that a divestiture of Grail would harm "the interest of the general public." Resp. Post-Tr. Br. at 278 (internal quotations omitted). As explained in Complaint Counsel's post-trial reply brief, *see* Complaint Counsel's Post-Trial Reply Brief § V, and in Complaint Counsel's post-trial brief, *see* Complaint Counsel's Post-Trial Brief § II.G.2., Respondents' alleged efficiencies are wholly inadequate to rebut Complaint Counsel's *prima facie* case and, thus, are also insufficient to avoid the "natural remedy" of a divestiture. *du Pont 1961*, 366 U.S. at 329. Further, in passing the Clayton Act, Congress determined that the public interest is served by competition. *See FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967) ("Congress was aware that some mergers which lessen competition may also result in economies

but it struck the balance in favor of protecting competition."); *Brown Shoe*, 370 U.S. at 344 (stating that "we cannot fail to recognize Congress' desire to promote competition"). Here, restoring the status quo through a divestiture of Grail's standalone business will both preserve competition in the research, development, and commercialization of MCED tests and, through such competition, will lead to improved cancer screening tests that will save countless lives. Therefore, the Proposed Conclusion should be disregarded.

156. But even assuming these efficiencies are discounted, a divestiture will remove the undisputed financial security that the Transaction has brought to GRAIL. Despite its tremendous progress to date, GRAIL faces many challenges which will require significant funding. For example, it is undisputed that continuing the population-scale clinical trials that GRAIL and now Illumina have undertaken to date will cost millions, if not hundreds of millions of dollars. (PFF ¶ 2129 (PX7138 (Scott Morton Trial Dep. at 319).)) Similarly, as Respondents have described above, Illumina will need to spend millions of dollars to accelerate Galleri's FDA approval and achieve widespread payor reimbursement for Galleri. The Transaction has provided GRAIL with critical funding that it needs in order to achieve these goals. (*See, e.g.*, PFF ¶ 1629.1.)

Response to Proposed Conclusion No. 156

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is incorrect, contrary to the weight of the evidence, and misleading to the extend it suggests Grail will suffer financially absent the Acquisition. Prior to the Acquisition Grail was backed by significant investors including Jeff Bezos and Bill Gates, (CCFF ¶ 5855), and had successfully raised $1.9 billion in funding, (CCFF ¶¶ 5850-51). Without help from Illumina, Grail alone was able to raise funds, develop its MCED test, perform large-scale clinical studies, and market and sell its test to customers. *See* Complaint Counsel's Post-Trial Brief § I.B. [redacted]

[redacted] And, should the Acquisition be undone, investors have already expressed an interest in "making a more significant investment in Grail." (CCFF ¶ 195). Accordingly, Grail itself says that it will be "well positioned for any outcome." (CCFF ¶ 196). Because the weight of the evidence contradicts Respondents' purported conclusion, the Proposed Conclusion should be disregarded.

157. Under the unique circumstances of this case, divestiture would be fundamentally inequitable to Respondents. Divestiture is an equitable remedy, *E. I. du Pont de Nemours & Co.*, 366 U.S. at 326, and "the current situation is always relevant to the question of equitable relief," Areeda & Hovenkamp, *Antitrust Law* ¶ 1205a. "Economic hardship" to Respondents is appropriately considered when choosing among "effective remedies", and the Supreme Court has long held that a remedy must take "proper regard for the vast interests of private property which may have become vested in [for example, stockholders] as a result of the acquisition . . . without any guilty knowledge or intent." *du Pont*, 366 U.S. at 327–28.

Response to Proposed Conclusion No. 157

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition.

The Proposed Conclusion is contrary to the law. "[I]t is well settled that the Commission may order full divestiture in a consummated merger case when a violation of the Clayton Act has been found." *Otto Bock*, 2019 WL 2118886, at *55 (Chappell, A.L.J.). "[C]ourts are authorized, indeed required, to decree relief effective to redress the violations, whatever the adverse effect of such a decree on private interests." *du Pont 1961*, 366 U.S. at 326; *see also Otto Bock*, 2019 WL 2118886, at *57 (Chappell, A.L.J.). Thus, "[t]he mere fact that divestiture may have an adverse economic impact on Respondent does not compel a lesser remedy." *In re Polypore Int'l, Inc.*, 149 F.T.C. 486, 949 (F.T.C. Mar. 1, 2010). And here any costs to Respondents of unwinding the consummated Acquisition are entirely of their own doing. (CCFF ¶¶ 218-22) (Illumina explaining to investors that it closed the Acquisition despite knowing that doing so could result in the imposition of "fines, penalties, remedies or restrictions" by government or regulatory

authorities). As the Fourth Circuit explained "if courts were required to choose the remedy least burdensome to the defendant—rather than the one that best promotes competition—conduct remedies would be the norm because they generally burden defendants less." *Steves & Sons*, 988 F.3d at 720. But, the court added, "that would go against Congress's policy judgment that divestiture is 'the remedy best suited to redress the ills of an anticompetitive merger.'" *Steves & Sons*, 988 F.3d at 720 (quoting *Cal. v. Am. Stores Co.*, 495 U.S. 271, 285 (1990)).

158. Here, it is undisputed that a divestiture would affect private property interests. Indeed, attempting to reverse this billion dollar Transaction would be a significant undertaking. More important, allowing the Commission to order a divestiture after it withdrew its complaint seeking a preliminary injunction in federal court would be inequitable. At the outset of this case, Respondents agreed not to close the Transaction while the Commission's preliminary injunction complaint was adjudicated by a federal court. The Commission later withdrew its preliminary injunction and allowed the Transaction to close under U.S. law. It would be fundamentally unfair for the Commission to order a divestiture of a Transaction it affirmatively decided not to prevent. This is especially the case where, as here, there are narrower and less costly remedies available.

Response to Proposed Conclusion No. 158

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is unsupported, contrary to the law, and misleading to the extent it imp-lies that a divestiture is unwarranted because "a divestiture would affect private property interests," for the reasons provided in Response to Proposed Conclusion No. 157. "[C]ourts are authorized, indeed required, to decree relief effective to redress the violations, whatever the adverse effect of such a decree on private interests." *du Pont 1961*, 366 U.S. at 326; *see also Otto Bock*, 2019 WL 2118886, at *57 (Chappell, A.L.J.). Thus, "[t]he mere fact that divestiture may have an adverse economic impact on Respondent does not compel a lesser

remedy." *In re Polypore Int'l, Inc.*, 149 F.T.C. 486, 949 (F.T.C. Mar. 1, 2010).

The Proposed Conclusion that it would be "unfair" and "inequitable" to order a divestiture because the Commission withdrew its preliminary injunction in federal court is incorrect and contrary to the law. It appears Respondents misunderstand the purpose of preliminary injunctions. As the Commission explained in its motion to dismiss the preliminary injunction in federal court:

> [t]he FTC is authorized to seek a preliminary injunction or temporary restraining order *only if* necessary to preserve the *status quo*. The EC's prohibition on closing now moots the FTC's PI Complaint as no temporary restraining order or preliminary injunction is currently needed to maintain the *status quo* pending the administrative trial. Therefore, the FTC moves to dismiss its Complaint without prejudice because relief is not necessary at this time.

Pl.'s *Ex Parte* Application To Dismiss the Complaint Without Prejudice, 6, *FTC v. Illumina, Inc. and Grail, Inc.*, No. 3:21-cv-00800 (S.D. Cal. May 21, 2021) (Dkt. 120) (emphasis added). At that time, Complaint Counsel was unaware that Respondents would take the unprecedented step of closing the Acquisition despite the EC's prohibition against doing so. (CCFF ¶¶ 218-22).

CONCLUSION

159. For these reasons, Complaint Counsel's attempt to unwind the reunion of Illumina and GRAIL is rejected and judgment is entered in favor of Respondents.

Response to Proposed Conclusion No. 159

This is not a proposed conclusion of law because it does not expound on any legal standard or proposition. Moreover, it is unsupported by any legal authority or record evidence as required by the Court's March 23, 2022 Order on Post-Trial Filings, at 2. Consequently, it should be disregarded.

The Proposed Conclusion is contrary to the law and contrary to the weight of the evidence for the reasons explained in Complaint Counsel's post-trial brief and post-trial reply brief.

Dated: June 2, 2022

Respectfully submitted,

s/ Jordan S. Andrew
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CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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