# 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** 

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William P. Rogerson, Modelling and Predicting the Competitive Effects of Vertical Mergers: The Bargaining Leverage over Rivals (BLR) Effect (Feb. 28, 2020)

#### **INTRODUCTION**

Complaint Counsel and Respondents agree that the stakes of this case are thousands of potential lives saved. Numerous multicancer early detection ("MCED") tests are poised to revolutionize cancer care by allowing the detection of cancer at early stages when it can be better treated and cured. Preserving an even playing field for the many companies currently competing to research, develop, and offer the best performing, most accurate MCED test to American patients will save thousands of lives. Through its acquisition of Grail (the "Acquisition"), Illumina smothers this competition, arresting innovation just as it is poised to deliver life-changing technology to millions of Americans by consolidating early cancer detection in the hands of one company and denying patients the life-saving benefits of competition.

and explain how Illumina's bet-the-company strategy to acquire Grail drives Illumina to do everything it can to capture the \$60 billion MCED market opportunity Illumina promised its shareholders. The overwhelming evidence shows that the combination of Illumina and Grail will lead to only one outcome—diminished competition in the research, development, and commercialization of these life-saving tests in the United States.<sup>1</sup>

Rather than address Complaint Counsel's arguments head-on with record evidence, Respondents raise four primary arguments: (1) Galleri is so differentiated from other MCED tests that the combined Illumina/Grail lacks an incentive to disadvantage other MCED test developers; (2) entry from other alleged NGS developers (primarily BGI) would prevent competitive harm; (3) Respondents' Open Offer remedies the harm; and (4) the Acquisition will result in efficiencies. Each of these key claims is riddled with unsupported statements, misleading assertions, and misapplications of legal and economic principles.

First, one of Respondents' primary arguments is that Grail's Galleri test will not face any MCED test competition because, unlike other MCED tests, Grail "has demonstrated it can simultaneously screen for more than 50 types of cancer in asymptomatic patients and accurately localize the cancer in positive cases (*i.e.*, detect cancer signal of origin)." Resp. Post-Tr. Br. at 2. This oft-repeated claim, which underpins many of Respondents' arguments regarding market definition and effects, is simply false. Grail's own clinical studies show that Galleri has only demonstrated the ability to screen for *seven* early-stage cancers in asymptomatic patients. *See, infra*, § I.B.2.b.ii.a; *see also* (Ofman (Grail) Tr. 3297-98); (Cote Tr. 4000-01); (CCFF ¶¶ 6206-

<sup>&</sup>lt;sup>1</sup> Respondents do not contest Complaint Counsel's allegation that "[t]he United States is the relevant geographic market to assess the competitive effects of the Acquisition." Complaint, *In re Illumina, Inc. and Grail, Inc.*, Docket No. 9401, ¶ 37 (F.T.C. Mar. 30, 2022) [hereinafter "Complaint"]; Resp. Post-Tr. Br.

6394). This is even fewer than one of Grail's key rivals—Exact. *See* (CCFF ¶ 2050). Similarly, Respondents claim that Galleri does not require follow-up imaging, unlike rival MCED tests, when Grail's own website makes clear that it "requires confirmatory diagnostic evaluation" through follow-up procedures such as imaging. (PX0063 at 002 (Galleri webcapture)); *see also* (CCFF ¶¶ 3565-69).

Second, another of Respondents' key arguments is that entry by BGI will preclude Illumina from disadvantaging Grail's rivals because they could allegedly switch from Illumina's NGS platform to BGI's platform. However, this claim, like several of Respondents' other claims to this Court, directly contradict Respondents' public statements and court filings in other proceedings. For example, in their post-trial brief, Respondents assert that { Resp. Post-Tr. Br. at 77. However, just two months prior in February 2022, Illumina informed a federal court that BGI's technology is "unproven and immature." Pl.'s Reply in Support of Mot. for Permanent Inj. at 10, *Illumina*, Inc. v. BGI Genomics Co., Ltd., Docket No. 3:19-cv-03770 (N.D. Cal Feb. 16, 2022). Similarly, Respondents argue to this Court that "BGI will enter the U.S. market not long after Illumina's patents that underlie the injunction against BGI's entry expire in 2023." Resp. Post-Tr. Br. at 125. But Illumina's Chief Technology Officer Alex Aravanis told investors, "[a]s we learn more about BGI's products, additional patents may become relevant," because Illumina has additional patents touching "every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics." (CCFF ¶ 1284).

Third, Respondents argue that even if there is competitive harm, the Open Offer fully erases it. While Complaint Counsel has put forward testimony from each MCED test developer

describing the intrinsic faults of the Open Offer, Respondents merely rehash the text of the Open Offer's provisions and rely solely on paid expert testimony as to the Open Offer's benefits, in direct contradiction to testimony from the actual customers who would be subject to its terms. *See, infra*, § IV. Rather than restore the competitive harm lost from the Acquisition, the Open Offer is an Illumina-drafted, non-negotiated contract that Respondents seek to impose on all of Illumina's clinical oncology customers, even if customers would not have otherwise signed it or could have obtained more favorable terms without it. *See, e.g.*, (CCFF ¶ 4396, 4447-48). Respondents even admit that the Open Offer is incomplete, its terms are "flexible," and it has yet to be operationalized, confirming its ineffectiveness as a remedy. Resp. Post-Tr. Br. at 153, 173.

Finally, Respondents make the blanket statement, without support, that the Acquisition "will save countless lives and billions of dollars." Resp. Post-Tr. Br. at 2. Respondents, however, fail to substantiate any of their efficiency claims beyond broad pronouncements that vertical mergers lead to efficiencies and vague assertions from their own executives and experts. *See, infra,* § V; *see also* Resp. Post-Tr. Br. at 181 ("[E]ach [purported efficiency] was supported by every Illumina and GRAIL witness to testify about them."). Relying only on self-serving executive testimony, though, is not sufficient. As post-acquisition evidence from *AT&T/Time Warner* teaches (a case upon which Respondents heavily rely), executives' unsubstantiated claims at trial often do not translate into reality. Respondents' own experts, one of whom was the economic expert in that case, even admit that the efficiencies claimed by the executives in *AT&T/Time Warner* were never realized. (PX7134 (Carlton Dep. at 43, 57)) (testifying that "AT&T did not achieve what it hoped to achieve" and "that the parties thought [it] would produce an efficiency, though it ultimately didn't"); *see also* (PX0398 at 022 (Interview with Dr. Katz,

"Michael Katz on Challenges to Antitrust Policy")) ("But I think what's turned out to be the case with [the AT&T/Time Warner merger] is that the vertical synergies that the parties claimed turned out not to be as big as they thought."); *infra* § V.

Unable to undermine the substantial record evidence demonstrating that the Acquisition provides Illumina with the ability and incentive to disadvantage Grail's MCED rivals to secure the massive MCED market, Respondents ask this Court to adopt a novel legal standard for vertical mergers that would render vertical merger enforcement essentially nonexistent. Under Respondents' artificial legal standard, vertical merger enforcement could only exist with a proven upstream monopolist and a fully formed downstream market devoid of future innovation or change. See, infra, §§ I, II.A. To support this irrational standard, which is contradicted by decades of vertical merger precedent, Respondents instead focus on cases brought under Section 2 of the Sherman Act (which addresses illegal monopolization claims) in their brief. For example, Respondents rely primarily on Section 2 cases to argue that Complaint Counsel must prove an upstream related product market, even though Complaint Counsel only alleges harm in the downstream market for the research, development, and commercialization of MCED tests. See Resp. Post-Tr. Br. § I.B.1; see also, infra, § II.A. Respondents' Section 2 cases, however, 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."). Even when citing to cases

applying the correct legal standard, Respondents misquote and misinterpret the law. *See, e.g.*, Resp. Post-Tr. Br. at 153-54 (citing three cases involving structural divestitures as "remedies like the Open Offer"); Resp. Post-Tr. Br. at 73 (citing *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109 (D.D.C. 2004), for the proposition that "proof of a related product market is an element of Complaint Counsel's case" even though *Arch Coal* is a horizontal merger case with no related product or reference to a related product market).

Respondents likewise fail to find independent economic support for their assertions.<sup>2</sup> While Respondents cite to several economic articles throughout their post-trial brief, these articles do not actually support Respondents' claims. For example, Respondents argue that the legal standard in vertical mergers should be different from horizontal mergers because "most vertical mergers are procompetitive." Resp. Post-Tr. Br. at 87-88. But Respondents' own cited economic literature rebukes these claims. *See, e.g.*, Jonathan B. Baker, Nancy L. Rose, Steven C. Salop & Fiona Scott Morton, *Recommendations and Comments on the Draft Vertical Merger Guidelines*, 17 n.24 (Feb. 24, 2020) ("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."); Gregory S. Crawford et al., *AT&T/Time Warner and Antitrust Policy Toward Vertical Mergers*, CPI, Antitrust Chron 3 n.5 (July 2019) ("We feel that a more nuanced and cautious view is warranted: if it was inexorable that integration enhances efficiency, the Soviet Union would

<sup>&</sup>lt;sup>2</sup> With a dearth of legal or academic support, Respondents attempt to circumvent this Court's orders regarding the proper procedures for expert testimony and cite extensively to an article by Bruce Kobayashi and Timothy Muris, which Respondents present as an independent economic and legal perspective on the Acquisition. A closer look, though, reveals that Illumina {

and Illumina provided comments on the authors' drafts. *See, infra*, § III.A.1. The article does not represent independent theory, but instead "serv[es] as a mere conduit for the views of one of the parties" in conflict with this Court's instruction. *In re Illumina, Inc. and GRAIL, Inc.*, Order Denying Motion for Leave to File Amicus Curiae Brief, Docket No. 9401 at 2 (Nov. 5, 2021) (quoting Charles Wright & Arthur Miller, *Fed. Prac. & Proc. Juris.* § 3975 (5th ed. 2022)).

have been the most efficient economy ever."). Respondents also use the Baker, Rose, Salop, and Scott Morton commentary to support their claim that Complaint Counsel must define a related product market when, instead, the article explicitly *rejects* this argument. *See, infra,* § II.A.

Even if any arguments in Respondents' Post-Trial Brief had theoretical merit, a review of the proposed findings that Respondents cite for these arguments reveals that the claims are devoid of factual support in the evidentiary record. For example:

- Respondents repeatedly violate this Court's orders by citing to demonstratives, *see, e.g.*, (Response to RPFF ¶¶ 368.1, 422, 430.1, 439.1, 442, 446, 459).
- Respondents misattribute sources of documents, *see*, *e.g.*, (Response to RPFF ¶¶ 161, 191, 472, 587, 589-92, 594.2, 596, 598-99, 600.3, 600.4, 602, 604, 604.1, 652, 667-69, 672.1, 672.2, 673-74). For example, one of Respondents' proposed findings copies and pastes a portion of one of Respondents' expert reports (Dr. Cote) but instead cites only to a single document that Respondents improperly attribute to the FDA. *See* (Response to RPFF ¶ 672.2). It is unclear where Respondents obtained the document, but it was not produced by the FDA as the FDA did not provide evidence in this matter.
- Respondents repeatedly cite to expert testimony for factual claims, *see*, *e.g.*, (Response to RPFF ¶¶ 81, 82-107, 122-39, 422, 444, 457, 470-71, 580, 588, 784, 943). For example, Respondents cite only to one of the experts, Dr. Cote—rather than MCED test developers or BGI itself—for the factual claim that "BGI's NGS sequencers use an SBS technology that is similar to Illumina's NGS sequencing technology." (RPFF ¶ 588). Fact witness testimony overwhelmingly contradicted Dr. Cote's factual claim, with third parties explaining that BGI's technology is inferior to Illumina's. (Response to RPFF ¶ 588).
- Some proposed findings are simply devoid of any evidentiary support as they do not cite to any testimony, documents, or other record evidence at all, *see*, *e.g.*, (Response to RPFF ¶¶ 726.3, 780, 793, 846).

Additionally, numerous proposed findings misstate or misrepresent the substance of the cited support. *See, e.g.*, (Response to RPFF  $\P$  159.2, 468, 612, 624, 709.3, 735, 758, 784.6, 801.1, 998.5, 1047.4, 1699, 1812). For example:

• Respondents make the factual assertion that {

$\{RPFF \mid 612\}$ . But <i>none</i> of the MCED test developers testified that their MCED
tests would work on the { }. Respondents cite only to {
} who testified based solely on his own view; he did not
even suggest that other test developers shared this view. (Response to RPFF ¶ 612). In
fact, one of the few MCED test developers that even knows anything about {
}

- Respondents make the factual claim that Grail's former 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." (RPFF ¶ 709.3). Bishop, however, testified that he *did not know* if Exact/Thrive or Singlera's MCED tests would compete with Galleri. *See* (Response to RPFF ¶ 709.3) (citing Bishop (Grail) Tr. 1397, 99). With respect to Guardant and Freenome, Bishop only testified about their *single-cancer* screening tests and did not opine on how their MCED tests would compete with Galleri. *See* (Response to RPFF ¶ 709.3).
- Respondents make the claim that Guardant's SVP of Commercial, Cancer Screening Core William 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." (RPFF ¶ 1823). The testimony that Respondents cite to only shows Getty acknowledging that he sees a line in Guardant's 10-K annual report in which Guardant notes that Thermo Fisher may offer a liquid biopsy test in competition to Guardant. (PX0060 (Guardant) at 014 (Guardant 10-K for fiscal year ending Dec. 31, 2020)). Contrary to Respondents' misleading assertion, Getty explicitly testified that Guardant cannot run its MCED test on Thermo Fisher's platform. (Getty (Guardant) Tr. 2688). Getty also testified that there are no other companies, besides Illumina, developing NGS platforms that Guardant could use for its MCED test. (Getty (Guardant) Tr. 2688).
- Respondents make the factual claim that "Mr. Conroy [Exact's CEO] admitted that Exact/Thrive's CancerSEEK is not a substitute for, but is highly differentiated from, GRAIL's Galleri test." (RPFF ¶ 1699). But when Conroy was asked by Respondent counsel whether CancerSEEK and Galleri were complements, he replied that he "was at a loss" to understand how patients would benefit from taking both Galleri and CancerSEEK tests. (Conroy (Exact) Tr. 1710-11); see also (Response to RPFF ¶ 1699). Instead, Conroy

Finally, some of Respondents' proposed findings misattribute the source of the testimony, incorrectly suggesting that fact witnesses were the source of claims rather than Respondents' experts. For example, Respondents copy and paste an unsupported passage from one of their expert's reports (Dr. Cote) about { }, but instead of attributing the claim to the expert report from which it was taken, Respondents misattribute Dr. Cote's own words to Exact's CEO, Kevin Conroy, whose testimony does not support the finding. (Response to RPFF ¶ 441). Respondents do the same with several other unsupported claims from Dr. Cote's report. *See, e.g.*, (Response to RPFF ¶¶ 428, 658, 677.2, 678.4-5).

Recognizing they lack record evidence to support their arguments, Respondents attempt to turn this proceeding into a trial-by-expert, using eight paid witnesses to fill in "evidence" that Respondents were unable to elicit from fact witnesses. In fact, in Respondents 2,206 proposed findings of fact, they cite to their eight paid experts 1,720 times. While doing so, Respondents repeatedly violate this Court's admonition against citing expert testimony to support factual propositions that should be established by fact witnesses or documents. For example, despite repeating the argument that there will be "a flood of upstream competition in the near future," Resp. Post-Tr. Br. at 80, Respondents chose to call only one NGS platform developer at trial—Singular. Respondents never subpoenaed documents from BGI, never deposed any BGI executives, and never called anyone from BGI at trial, despite featuring BGI heavily in their post-

trial brief.<sup>3</sup> Instead, Respondents simply use their own expert, Dr. Cote, to fill in the many gaps where they failed to present unbiased fact witness testimony and documentary evidence. For instance, Respondents rely solely on Dr. Cote for their argument that { Resp. Post-Tr. Br. at 78. Fact witness testimony, including from { and MCED test developers, unequivocally rebuts this claim. See { (CCFF ¶¶ 1229-68); see also, (Response to RPFF ¶ 779) (Respondents rely solely on Dr. Cote for the claim that "Oxford Nanopore is also a viable alternative for MCED developers" in contrast with extensive fact witness testimony.).

Actual evidence from market participants shows that Illumina's acquisition of Grail is illegal. If this Acquisition is allowed to proceed, Illumina—rather than the free market—will serve as the gatekeeper determining which MCED tests (if any besides Galleri) will be available to American consumers. Complaint Counsel has met its burden with an extremely strong *prima facie* case, buttressed by extensive testimony from numerous MCED developers and other market participants and reinforced by ordinary course documents from Illumina and Grail. Respondents have failed to rebut Complaint Counsel's case. With respect to every defense raised, Respondents' evidence falls far short of the law's requirements. Thus, the divestiture of Grail's business from Illumina's full ownership is justified here to prevent harm to competition. Complaint Counsel respectfully requests this Court issue its Proposed Order.

<sup>&</sup>lt;sup>3</sup> Respondents could have easily obtained evidence from BGI for this proceeding if they had wanted to present such evidence. *See Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at \*25 (N.D. Cal. Mar. 27, 2022) (noting Illumina's deposition of Jian Wang, BGI's Chairman: "Q: Do you consider the CoolMPS sequencers to be an important product line of BGI? A: No.").

# I. Complaint Counsel Properly Defined a Relevant Product Market for the Research, Development, and Commercialization of MCED Tests

Complaint Counsel has alleged 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 ¶ 31; see generally CC Post-Tr. Br. § II.E. Respondents attack Complaint Counsel's market definition by arguing that (a) Complaint Counsel has failed to properly define the market; (b) MCED tests in development are not "reasonably interchangeable"; (c) the Brown Shoe practical indicia point to a narrower relevant market; (d) Complaint Counsel has not shown that its relevant market will pass the Hypothetical Monopolist Test; and (e) Complaint Counsel improperly alleges harm to innovation. When viewed properly through the lens of the alleged harm as instructed by the Supreme Court, each of Respondents' arguments fail. See Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962) ("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.").

Section 7 of the Clayton Act prevents mergers "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. "Determination of the relevant market is a necessary predicate to a finding of a violation of the

<sup>&</sup>lt;sup>4</sup> A relevant market consists of both a relevant product market and a relevant geographic market. Respondents do not contest Complaint Counsel's allegation that "[t]he United States is the relevant geographic market to assess the competitive effects of the Acquisition." Complaint ¶ 37; Resp. Post-Tr. Br.

Clayton Act." *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957). Market definition, however, 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 in both the research and development and the commercialization of MCED tests. CC Post-Tr. Br. § II.E. In support of its allegations, Complaint Counsel defined a relevant market—and produced evidence supporting its market—for the research, development, and commercialization of MCED tests. CC Post-Tr. Br. § II.B. 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.

Respondents, however, argue that Complaint Counsel has failed to meet its burden. While Respondents' arguments come in several permutations, they all rely on the same flawed premise: that Complaint Counsel has not (and indeed cannot) prove a relevant market because, as Respondents wrongly allege, the market for MCED tests is not mature and Grail's competitors do not yet have products for sale. Resp. Post-Tr. Br. at 19. Section 7 of the Clayton Act, however, is not limited to mature markets with multiple products for sale. Instead, Section 7 of the Clayton Act was specifically enacted to "arrest anticompetitive tendencies in their 'incipiency." *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208, 1213-14 (11th Cir. 2012) (quoting *United States v. Phila. Nat'l* 

Bank, 374 U.S. 321, 362 (1963)); see also FTC v. Proctor & Gamble Co., 386 U.S. 568, 577 (1967). Requiring a market to be defined around "fully developed" products contravenes that very purpose.

Further, Respondents' purported standard either assumes that competitive harm cannot occur prior to a market having multiple products for sale or that pre-sale competition is unworthy of the protections of antitrust laws. Economic theory, legal precedent, and the facts adduced in this case say otherwise. *See, infra,* § I.D; *see generally* (CCFF ¶ 1902-2605, 3189-3497) (collecting evidence demonstrating that other companies are developing MCED tests which compete with Grail's Galleri test). This Court should reject Respondents' proposal to deviate from well-established legal and economic principles and find that Complaint Counsel has properly defined the market around market realities. *FTC v. Peabody Energy Corp.*, 492 F. Supp. 3d 865, 892 (E.D. Mo. 2020) (discounting arguments that "ignore industry realities.") (quotations omitted).

# A. Complaint Counsel's Relevant Market Is Supported by Robust Evidence of Current Competition and Is Properly Focused on What Anticompetitive Effects Will Occur

Respondents first argue that Complaint Counsel's market definition is speculative because the defined market consists only of Galleri and other "products that are still in development, some in very early stages." Resp. Post-Tr. Br. at 19-20. Second, Respondents argue that the relevant market is both over-inclusive, because it includes tests beyond Galleri, and underinclusive, because it excludes MCED tests that are not based on NGS technology. Resp. Post-Tr. Br. at 27. Both of Respondents' arguments are unmoored in law, fact, or logic.

#### 1. Complaint Counsel's Defined Market Is Grounded by Overwhelming Evidence Showing Current Competition To Develop MCED Tests To Rival Galleri

Respondents argue that Complaint Counsel's market definition is "speculative" because the products are not yet commercialized and "[n]o one knows what features and functions they will have if they are sold." Resp. Post-Tr. Br. at 20. Specifically, Respondents claim that no other MCED test "will be like Galleri (50+ cancer types and accurate signal of origin detection) at any point in the foreseeable future." Resp. Post-Tr. Br. at 20. From the outset, Respondents' argument rests on a faulty foundation: that no current market exists for MCED tests. Resp. Post-Tr. Br. at 22-23. This is not the case. Rather, as Respondents acknowledge, "Grail commercially launched Galleri in May 2021," (RPFF ¶ 59), and at the time of trial Grail { and had engaged in discussions with over a dozen more private payers. (CCFF ¶ 89-91). 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).6

example, {

| See Respondents' misquoted or ill-founded testimony is similarly unavailing. See {

| PX7086 (Cance (ACS) Dep. at 51) (testifying to the narrow point that it would be speculating as to when an MCED test would replace the existing standard of care screening tests); {

<sup>&</sup>lt;sup>5</sup> As Complaint Counsel explains more fully *infra* § I.B.2.b.ii.a, Respondents overstate Galleri's characteristics and a more accurate assessment of the Galleri test shows that other MCED tests share key features with the Galleri test, leading Galleri to identify MCED test developers as current and future rivals. *See, infra*, § I.B.2.b.ii.

<sup>&</sup>lt;sup>6</sup> Respondents cite to misrepresented and out-of-context testimony to support their claim that the product market is "speculative." *See* Resp. Post-Tr. Br. at 20-21. Such misstatements are not probative and should be disregarded. For example,

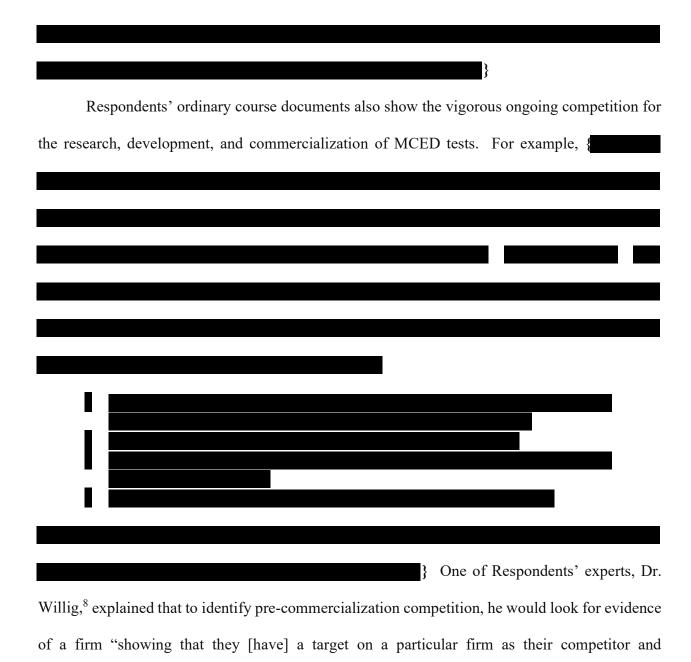
Despite this, Respondents wish to remove this Acquisition from the protections of the Clayton Act because Galleri's competitors are still in development and not yet for sale. Respondents' argument presupposes that Grail's MCED rivals are in the "early" stages of development. To the contrary, MCED witnesses have explained that commercialization is imminent. See, e.g., {

Moreover, the evidence shows—and Respondents admit—that MCED test developers invested substantially in their tests, which share core functionality with Galleri and are being designed to compete against it. *See, infra*, § I.B; (RX3871 (Willig Report, Table 1)).<sup>7</sup>

Second, by focusing on commercialization, Respondents ask the wrong question. Complaint Counsel has not alleged that Respondents will only have the ability and incentive to harm Grail's rivals once they are commercialized, but instead that Respondents also have the ability and incentive to harm Grail's rivals today as they research and develop their tests. Given that the purpose of market definition is to illuminate anticompetitive effects, the correct question is not solely when rival MCED tests will launch, but rather when MCED tests will be sufficiently

<sup>&</sup>lt;sup>7</sup> The precise contours of many, if not most, markets are subject to change as products develop and market participants change. Here, evidence shows that there are a multitude of MCED competitors nipping at Galleri's heels. Absent foreclosure, odds are that one, if not more, of these competitors will be meaningful competitors to Galleri, providing patients all the benefits of competition. Unbound by any limiting principles, Respondents' proposed standard would effectively eliminate antitrust enforcement in any dynamic market, which is contrary to well established caselaw. *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 49-50 (D.C. Cir. 2001) (noting that whether or not Microsoft was correct that it operated in a market where "entrenchment may be temporary, because innovation may alter the field altogether... does not appreciably alter our mission in assessing the alleged antitrust violations in the present case.").

developed that they present a clear competitive threat to Grail's Galleri test giving rise to an incentive to disadvantage Grail's rivals. *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."); see 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, the clear record evidence from Respondents' own documents and fact witness testimony shows that, today, Grail identifies other MCED test developers as competitive threats and has adjusted its development and commercialization plans to defend against these threats. (CCFF ¶¶ 3231-84, 3294-3307, 3319-25, 3335-50, 3358-61, 3370-75, 3381-88, 3389-3470). MCED test developers have done the same.



understanding what that other firm's products can do in terms of their characteristics and . . . are

racing against that other firm, the particular firm, to reach the marketplace with the—the requisite

<sup>&</sup>lt;sup>8</sup> While Complaint Counsel maintains that Respondents' continued reliance on the opinion of Dr. Willig contravenes this Court's order, to the extent this Court disagrees, Complaint Counsel contends that the Court should have the benefit of the full record surrounding his expert opinion. *See* (Response to RPFF ¶¶ 2006-21).

characteristics to its product in order to succeed against it." (PX7132 (Willig) Dep. at 117-118). As just described, the record is replete with just this evidence.

This competition is exactly why courts routinely hold that antitrust harm can occur—and should be protected—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 there 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). Here competition is not "speculative" or "aspiration[al]" as Respondents suggest. Resp. Post-Tr. Br. at 20. Instead, both third-party witness testimony and Respondents' ordinary course documents show that robust competition for the research, development, and commercialization of MCED tests exists today. (CCFF ¶ 1902-2606).

#### 2. The Boundaries of Complaint Counsel's Market Are Properly Defined

Respondents argue that Complaint Counsel's market definition is simultaneously over-inclusive and underinclusive. Resp. Post-Tr. Br. at 19-29. First, Respondents argue that Complaint Counsel's proposed market is over-inclusive because it could potentially include tests that detect only two or three cancers. Respondents suggest that an MCED test that detects only two or three cancers could not be a substitute for Galleri, which they (wrongfully) claim can screen for over 50 cancers. The market realities belie Respondents' concern. Respondents' argument

Ontrary to Respondents' assertion, Apartment Source is not illustrative. Resp. Post-Tr. Br. at 25-26 (discussing Apartment Source of Pa., L.P. v. Phila. Newspapers, Inc., 1999 WL 349938 (E.D. Pa. May 21, 1999)). 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 MCED test are a "separate economic reality" as shown by Complaint Counsel's application of the Brown Shoe practical indicia. CC Post-Tr. Br. § II.B.1.

rests on not just one, but two faulty premises. First, as explained in more detail *infra*, § I.B.2.b.ii.a(i), evidence from Grail's own clinical trials shows that Galleri has only been clinically validated to test for *seven* types of early-stage cancer in a screening population—far fewer than the 50 marketed by Respondents. (CCFF ¶¶ 6206-6394). Second, as MCED test developers testified at trial, {

compete with Grail on the number of cancers their tests detect,

}; (CCFF ¶ 3547) (Respondents' expert Dr. Abrams testifying that the exact number of cancers tested is just one factor that might cause him to switch between MCED tests). In fact, Exact (Grail's key rival) has already been clinically shown to detect eight cancers in an asymptomatic screening population, surpassing Galleri's seven. (CCFF ¶¶ 1940, 2050). Contrary to Respondents' assertions, Complaint Counsel's market does not include MCED test developers who are developing a test that detects "two or three" cancers, but rather the same, or a similar, number of cancers as Galleri. 10

<sup>&</sup>lt;sup>10</sup> Respondents further argue that "[i]n addition to clearly not being substitutes for *Galleri*, many of the tests in Complaint Counsel's proposed market are also not even substitutes for *each other*." Resp. Post-Tr. Br. at 26. Respondents, however, do not specify which tests they are referring to and only mention a hypothetical postulated by their expert, which is not grounded in actual evidence of MCED test developers' current or future plans. Moreover, Respondents yet again distract with the wrong question. 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* 

Second, Respondents argue that the product market is underinclusive because it fails to include MCED tests that do not rely on NGS technology. Resp. Post-Tr. Br. at 27-28. As with Respondents' over-inclusivity argument, this claim is similarly ungrounded in the record. Respondents alleged that StageZero, Genapsys Biolab's OneTest, InterVenn Biosciences, PrognomiQ, and Somalogic are all MCED test developers that should be included in market.

}. As far as the other tests go, Respondents' findings cite to no evidence that any of these other companies are developing an MCED test, nor that they are developing a test on non-NGS sequencers. (Response to RPFF ¶¶ 692-693). Rather, Respondents failed to introduce any evidence of these alleged competitors into the record and failed to call any of them as a witness in this matter. A complete examination of record evidence shows that Complaint Counsel's market definition is consistent with the market facts and grounded in legal precedent.

#### B. MCED Tests Are Reasonably Interchangeable

Respondents agree that a "properly defined product market includes the functionally similar products to which customers could turn." *Peabody*, 492 F. Supp. 3d at 884; Resp. Post-Tr. Br. at 29. Despite that, Respondents contend Galleri is not reasonably interchangeable with any of its MCED test rivals because (1) the other tests are not on the market; (2) the tests will not be commercialized for "many years"; and (3) there is no proof that customers will substitute Galleri

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). Here the relevant question is whether other MCED tests compete with Grail's Galleri test.

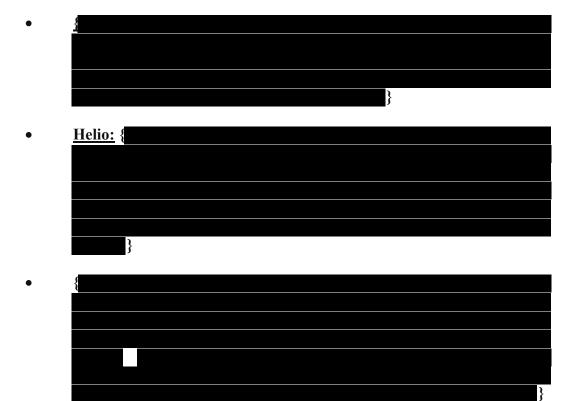
for its MCED rivals. Resp. Post-Tr. Br. at 29-40. Each of Respondents' arguments relies on a misapplication of fact and law.

# 1. The Evidence Shows That Galleri Is Reasonably Interchangeable With MCED Test Developer Products Regardless of Whether They Are on the Market

Respondents argue that because "there is no product in existence" and "[t]he prices and qualities of any other yet-to-exist products are not even specified" that Galleri cannot be reasonably interchangeable with other MCED tests. Resp. Post-Tr. Br. at 30. 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 impending 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.

{	
explained the	} Each MCED test developer dynamics of this competition to the Court under oath:
•	Exact/Thrive: {
	}
•	Guardant: Guardant testified that it views Grail, Natera, Exact, and Freenome as competitors in MCED development. (CCFF ¶ 3289). Guardant anticipates that its LUNAR-2 test will compete with Galleri and Guardant is "really focused" on Grail as a competitor. (CCFF ¶ 3290).
•	Freenome: {

• <u>Singlera:</u> Singlera's Gao testified that "Grail [is] doing something similar in direct competition with us." (Gao (Singlera) Tr. 2901). Singlera expects to compete against Grail's Galleri test on several levels, including efforts to "reduce cost, improve accuracy and improve convenience." (PX7042 (Gao (Singlera) IHT at 100)). "We have to innovate to survive." (PX7042 (Gao (Singlera) IHT at 100-01)).



Respondents ask this Court to discount consistent testimonial evidence for the illogical reason that MCED test developers are unreliable due to this very desire to compete with Grail. Resp. Post-Tr. Br. at 40-41. Setting this argument's faulty logic aside, Respondents' own documents show that their mischaracterization of MCED testimony as unreliable is not based on market facts, but rather on Respondents' multimillion dollar {

} Respondents'
derision of the motives of any adverse witness should be viewed with this backdrop in mind and
disregarded accordingly.
Despite consistency across MCED witness testimony, this Court need not rely on MCED
test developers' statements alone. Respondents' own ordinary course documents validate the
testimony of the MCED test developers by analyzing these very companies as Grail's key
competitors today and their tests as substitutes for Galleri in the near future. See, e.g., {
} For example, in a March 2020 presentation, Grail identified {
} and noted that Grail {

Grail's Director of Growth Marketing, Chris Della Porta, {

}. And in another ordinary course document, {

This 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 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).

## a. MCED Test Developers Are Well on Their Way to Commercialization

Respondents again try to distract from the robust evidence of current competition by highlighting the different commercialization timelines of MCED tests as evidence that the various tests are not reasonably interchangeable. Specifically, Respondents invoke Microsoft for the proposition that an MCED test must "enter the market" in a relatively short timeline to constrain Galleri's prices. Resp. Post-Tr. Br. at 30-37. But *Microsoft* was inapposite on this point. There, the D.C. Circuit was addressing the defendant's assertion that a product (middleware) might evolve 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). Respondents' position that this Court should ignore vigorous current competition merely because it is pre-commercialization, however, would effectively eliminate the ability for courts to protect consumers from anticompetitive precommercialization conduct, such as stifling an innovative product on the verge of launch, in contravention of well-established legal and economic precedent recognizing the benefits of such competition. See, infra, I.D. Respondents' argument is particularly troubling in a dynamic market such as this one. As Exact's CEO Conroy testified, {

Respondents also overstate commercialization timelines of Galleri's rival MCED tests, alleging that most of the MCED test developers are five to seven years away from launching their products. Resp. Post-Tr. Br. at 35. Respondents cite to the testimony of their expert—Dr. Cote—to support this statement and allege that MCED test developer statements support this testimony. Respondents, however, only cite to selective and out-of-context statements from MCED test developers. (Response to RPFF ¶ 701, 701.1-701.2, 701.4, 701.5, 701.6, 701.7, 702-702.5, 702.8, 703, 703.1, 703.2, 704, 704.1, 704.2, 705, 705.1, 705.2, 706, 706.1, 706.2, 706.3, 726.6, 726.7, 726.8, 836.5.2). An accurate assessment of testimony from MCED witnesses directly contradicts Dr. Cote's paid-for testimony. Resp. Post-Tr. Br. at 35-37. 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. {

}. 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. {
}; see also (Response to RPFF ¶¶ 701-
701.2, 701.4-701.7, 702-702.5, 702.8, 703-703.2, 704-704.2, 705-705.2, 706-706.1, 706.3, 726,
726.7-726.8, 836.5.2).
For example, while Respondents contend that due to Exact's acquisition of Thrive, Exact
must go "back to the drawing board" with the CancerSEEK test, Respondents' proposed finding
provides no support for this contention. (Response to RPFF ¶ 726.6). Instead, Conroy, the witness
best positioned to explain CancerSEEK's commercialization plans, {

Respondents' ordinary course documents also recognize that Exact (formally Thrive) is
For example, {
And in any one to the leavest desired Could consider the desired to
}. And in response to the looming threat, Grail considered whether it wanted to
}

In contravention of this evidence, Respondents seek to impose an artificially rigid and purportedly universal commercialization timeline based solely on the testimony of their expert, Dr. Cote, to allege that other MCED test developers will not be on the market for years. Specifically, Dr. Cote characterizes commercialization of an MCED test as a rigid six-step process lasting years. Resp. Post-Tr. Br. at 30-33. Dr. Cote, however, is wholly unqualified to offer an "expert" opinion on MCED commercialization given that he has no relevant training or experience, and his analysis on the subject is unsupported and unreviewed. *See* (Response to RPFF ¶ 1960) (examining Dr. Cote's complete lack of qualifications on subject of MCED development process

and timeline). Dr. Cote's purported expertise also directly contradicts evidence from MCED test
developers—witnesses actually qualified to testify about their commercialization process—who
testified about their different paths and timelines to commercialization, dependent on their varying
commercialization strategies and unique capabilities. 11 See, e.g., {
Most importantly, the record
evidence shows that Grail is competing with its MCED rivals while they are developing their tests
and preparing for commercialization. The robust evidence of current competition is strong
evidence that these products are reasonably interchangeable despite differences in their
commercialization timeline.

## b. While Not Required, Complaint Counsel Has Shown Evidence of Future Customer Substitution

Respondents allege that Complaint Counsel has failed to properly define a market because it has not shown evidence of customer substitution or cross-elasticity of demand. 12 Cross-elasticity of demand or customer substitution is often demonstrated by showing evidence of past customer switching. Here, evidence of past switching is not available. But that does not mean that Complaint Counsel has not shown evidence of customer substitution. Instead, the extensive documentary and testimonial evidence of similarity among MCED tests as well as evidence that MCED test developers and Respondents view each other as competitors indicates that in the future customer substitution will occur between Galleri and other MCED test developers. See, infra § I.B; see also (CCFF ¶¶ 3231-84, 3294-3307, 3319-25, 3335-50, 3358-61, 3370-75, 3381-84, 3389-93, 3424-68, 3471-92). Respondents' ordinary course documents identifying other MCED developers as competitors and tracking their progress would make no sense if they did not expect some degree of future substitution. In addition, market definition is a case-specific inquiry and must be analyzed in the context of the harm alleged. Brown Shoe, 370 U.S. at 325. Here, evidence of current customer substitution or cross-elasticity of demand is not dispositive on the operative issue of whether Respondents have the incentive to exercise their ability to disadvantage Grail's rivals in the research, development, and commercialization of MCED tests. This incentive can arise prior to the market maturing. As Grail's documents show, Grail has the incentive to solidify

<sup>&</sup>lt;sup>12</sup> 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).

Galleri's first-mover advantage by disadvantaging competing products before they are even
launched or, in Grail's own words, to {
}
c. Respondents Present No Credible Evidence Supporting Their Contention That Galleri Has No Reasonably Interchangeable MCED Rivals
Finally, Respondents cite to only two witnesses—and Gary Gao—who are not
either employees of the Respondents or paid experts to support their argument that Galleri is not
reasonably interchangeable with its MCED test rivals. Resp. Post-Tr. Br. at 39-40. Neither of
these witnesses' testimony is probative. First, Respondents allege that
Nolan—Freenome's current
CEO who actually has foundation to testify regarding Freenome's current MCED development
plans—explained that primary care providers would not use both Freenome's test and Galleri but
would choose one or the other. (Nolan (Freenome) Tr. 2727-28). When Conroy of Exact (another
MCED test developer) was asked by Respondents whether CancerSEEK and Galleri were

<sup>&</sup>lt;sup>13</sup> As explained in Complaint Counsel's responses to Respondents' Proposed Findings of Fact, Respondents' findings of fact are misleading and controverted by the weight of the evidence and should be disregarded. (Response to RPFF ¶¶ 709-709.6).

complements, he replied that he "was at a loss" to understand how patients would benefit from taking both tests. (Conroy (Exact) Tr. 1710-11). Respondents also do not provide the full context for Gao's testimony. While Gao testified that "I don't think there is a product yet. And I could not say how we are interchangeable right now," he nonetheless testified that he expects Singlera's MCED test to compete with Galleri. (PX7042 (Gao (Singlera) IHT at 98-99, 101)).

A holistic and accurate view of the record shows that MCED test developers are competing and will continue to compete with Grail. Grail itself tracks these companies and has recognized the threat they pose to Galleri's dominance in the MCED market. *See* (CCFF ¶¶ 3231-84, 3294-3307, 3335-50, 3358-61, 3370-75, 3381-84, 3389-3470). Respondents have provided no evidence rebutting the robust evidentiary record showing that Galleri shares key features and competes with other MCED tests. Complaint Counsel's application of the *Brown Shoe* practical indica further support the reasonable interchangeability of the Galleri test and other MCED rival tests.

### 2. Brown Shoe Practical Indicia Are Met Here

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 several "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. CC Post-Tr. Br. §

II.B.1. 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. CC Post-Tr. Br. § II.B.1.

While Respondents recognize the importance of the *Brown Shoe* practical indicia, Resp. Post-Tr. Br. at 41-42, they err in the application of these indicia. First, Respondents' application of the *Brown Shoe* factors dismisses evidence of current competition among MCED test developers. *See, e.g.*, (CCFF ¶ 3231-3284, 3294-3307, 3335-3350, 3358-3361, 3370-3375, 3381-3384, 3389-3470). Second, Respondents ignore or misstate key evidence—notably, their own documents and the testimony of MCED test developers—when analyzing the *Brown Shoe* practical indicia. Third, Respondents misapply several of the practical indicia.

# a. Complaint Counsel Properly Considered Whether MCED Tests Were in the Same Market as Galleri

Respondents appear to admit that diagnostic aid to cancer ("DAC") tests, minimal residual disease ("MRD") tests<sup>14</sup>, existing standard of care tests, and single-cancer tests are not in the relevant market. Resp. Post-Tr. Br. 63. While Respondents do not propose their own market definition, they nonetheless go on to argue that Complaint Counsel "overlooks and fails to address the key question" of whether the "MCED tests identified by Complaint Counsel are in the same relevant product market as Galleri." Resp. Post-Tr. Br. 63. As an initial matter, Respondents misunderstand the "key question" on market definition. Complaint Counsel alleges that the Acquisition poses a reasonable probability of substantially lessening competition in the market for

<sup>&</sup>lt;sup>14</sup> DAC tests are designed to confirm cancer diagnoses, while MRD tests are used to determine whether any cancer remains in the body post-treatment. (CCFF ¶¶ 150-52, 154-57).

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. Moreover, Respondents mischaracterize Complaint Counsel's market definition. 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; assessed whether MCED tests will have a distinct pricing apart from other oncology tests; and assessed industry recognition of MCED tests collectively. CC Post-Tr. Br. at 57-63. 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.

As Complaint Counsel's application of the *Brown Shoe* practical indicia shows, here the evidence proves that MCED tests are sufficiently interchangeable to constitute a relevant product market. *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 117 (D.D.C. 2016) ("In other words, a product market includes all goods that are reasonable substitutes, even where the products are not entirely the same."). Respondents' post-trial brief does not indicate otherwise.

# b. A Proper Application of the Brown Shoe Practical Indicia Supports Complaint Counsel's Market Definition

i. Industry Recognizes MCED Tests as a Distinct Market

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."). Here, Respondents admit that Galleri is on the market and that there are a "number of companies working to develop" MCED tests. Resp. Post-Tr. Br. at 43. Respondents also admit that industry experts distinguish between single- and multi-cancer tests, reinforcing industry recognition of Complaint Counsel's market definition. Resp. Post-Tr. Br. at 44; see also (PX2022 (Illumina) at 26 (Cowen: The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 2020)) (analyzing multi-cancer screening separately). But Respondents claim that because industry analysts cannot identify every MCED developer or their development status, this Brown Shoe factor fails. Resp. Post-Tr. Br. at 43-44. This argument is nonsensical. Respondents appear to be confusing market definition with identification of market participants. Taken to the extreme, Respondents' analysis would indicate that if the industry analysts could not identify every single gas station than there is no market for gas stations. This purported analysis defies both logic and common sense. From a practical standpoint, it is unsurprising that industry analysts are unaware of MCED test developers' confidential development plans, and knowledge of these plans are irrelevant to whether this factor is met.<sup>15</sup>

Respondents ignore the vast array of evidence from a multitude of industry participants showing industry recognition of the MCED test market. For example, Congress has identified MCED tests as a separate market (CCFF ¶ 809-821); the American Cancer Association has identified MCED tests as a separate market (CCFF ¶ 469-470); and MCED test developers identify MCED tests as a distinct market (CCFF ¶ 777-808). The U.S. House of Representatives and Senate introduced the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020 (explicitly recognizing the existence of the MCED industry) which states that MCED tests "can complement the covered early detection tests," rather than replace them. (CCFF ¶ 809). Cowen—a financial services firm— also identified multi-cancer screening tests targeted at asymptomatic patients as its own market and assessed that it would have approximately a \$5 to \$50 billion total addressable market in its report on liquid biopsy. (CCFF ¶ 820). Moreover, Respondents' own ordinary course documents analyze and assess MCED tests as a separate market. (CCFF ¶ 746-776). For example, Grail in a report summarizing developments from a popular medical conference explained: "MCED evolving into

<sup>&</sup>lt;sup>15</sup> Respondents point to the lack of clinical trials as somehow indicative of lack of industry recognition for a separate market. Again, this misses the point. This *Brown Shoe* factor deals with whether the industry differentiates between different markets, not whether the industry is aware of the development status of each and every market participant. Moreover, Respondents' analysis of the status of MCED test developers' clinical trial status is misleading as explained in Complaint Counsel's reply findings. (Response to RPFF ¶¶ 719, 720, 721, 721.1, 721.2, 721.3, 721.4).

a highly competitive landscape, though many seem to be starting with one cancer type, with intent to add more." (CCFF ¶ 767). In another example, Grail's corporate communication plan for Galleri's launch was intended to {

(CCFF ¶ 742). See also (CCFF ¶¶ 732-745). As Jeff Huber—Grail's former CEO—said in reaction to Thrive's anticipated launch, it was "good to have a 'market' instead of a single company, and now we have a market. It'll also mean there will be others pushing the rock up the hill for reimbursement—which is a very good thing." (CCFF ¶ 738).

These documents, in particular, reveal the contours of competition from the view of the market participants, who may be presumed to "have accurate perceptions of economic realities." *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1045 (D.C. Cir. 2008) (Tatel, J., concurring); *H&R Block*, 833 F. Supp. 2d at 52 (explaining that in determining the relevant product market, particular attention should be paid "to the defendants' ordinary course of business documents"). <sup>16</sup>

### ii. Peculiar Characteristics and Uses

Courts also look at the peculiar characteristics and uses of different products in assessing the relevant product market. *See, e.g., Brown Shoe,* 370 U.S. at 325 (explaining that men's, women's, and children's shoes each have peculiar characteristics). Respondents highlight alleged differences in MCED tests in an attempt to rebut Complaint Counsel's market definition, but these

<sup>&</sup>lt;sup>16</sup> In the face of extensive merger case law supporting the use of real-world evidence on industry recognition, Respondents can muster only cases that 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); *see, supra,* n.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. None of these cases held that industry recognition is irrelevant in a Clayton Act Section 7 case—nor could they, for the Supreme Court has clearly instructed that it is. *Brown Shoe Co.*, 370 U.S. at 325.

differences are overstated.<sup>17</sup> An accurate assessment shows that Galleri shares core features with its MCED test rivals.

### a) Respondents Misstate Galleri's Capabilities

In the first instance, Respondents argue that "[n]o other test does what Galleri can do," alleging that it can "simultaneously screen for more than 50 types of cancer in asymptomatic patients and accurately localize the cancer in positive cases (i.e., detect cancer signal of origin)." Resp. Post-Tr. Br. at 2. Respondents also argue that only Galleri can identify tissue of origin without a PET-CT scan and only Galleri has the requisite sensitivity and specificity. See Resp. Post-Tr. Br. at 48, 53, 57. Respondents return to this theme again and again, in an effort to suggest that Galleri is so differentiated from other MCED tests in development that it is in a market of its own. Given the overwhelming evidence that Grail and other MCED developers view one another as competitors, it is understandable that Respondents would seek to divert the Court's attention away from that evidence and towards a technical argument about specific product features. The problem for Respondents is that their technical argument is without merit or foundation. Respondents argue that Galleri is a "Lamborghini," implying that their MCED product is wildly superior to all other MCEDS, which they denigrate as mere "Chevrolets." See Resp. Post-Tr. Br. at 29-30 ("Chevrolets and Fords might be interchangeable in this sense, but Chevrolets and Lamborghinis are probably not.") (citing *ProMedica Health Sys. v. FTC*, 749 F.3d 559, 565 (6th

<sup>&</sup>lt;sup>17</sup> Dr. Cote, one of Respondents' experts explained that {

<sup>} (</sup>PX7131 (Cote Dep. at 276 (in camera)). Dr. Cote's

standard, however, is nonsensical and stands in direct contradiction to case law which simply requires products to be "reasonable substitutes," not identical ones. *Staples*, 190 F. Supp. 3d at 117 ("In other words, a product market includes all goods that are reasonable substitutes, even where the products are not entirely the same.").

Cir. 2014)). But the facts clearly demonstrate that the Galleri MCED test is far more similar to other MCED tests than Respondents claim. All MCED developers seek to offer a product that fulfills the same purpose: to detect multiple cancers in asymptomatic patients through a blood draw. *See* 2B Phillip E. Areeda, Herbert Hovenkamp & John L. Solow, Antitrust Law ¶ 533e at 259 (3d ed. 2007); *Arch Coal*, 329 F. Supp. 2d at 119 ("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.").

(i) <u>Galleri Has Only Been Clinically Shown To Detect Seven Types of</u> <u>Stage I-III Cancer in a Screening Setting, Not 50+</u>

As Respondents acknowledge: "GRAIL's multi-cancer early detection test, Galleri, is designed as a screening test for asymptomatic individuals over 50 years of age." (RPFF  $\P$  59); *see also, e.g.*, (RPFF  $\P$  342) (stating that Galleri "is designed to detect cancer . . . before a patient ever shows symptoms"). That definition encompasses two core clinical concepts:

- (1) the ability to detect cancers "early"; and
- (2) the ability to do so as a "screening test" in an "asymptomatic" population.

One of the most important attributes of a screening test is the ability to detect cancers at relatively early stages. (Conroy (Exact) Tr. 1701); *see also* (PX4178 (Grail) at 009 (Nephron Healthcare Investment Research, "ILMN – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020) ("The goal of screening is to find cancers early, before they metastasize and become a bigger problem.")); (CCFF ¶¶ 6222). Stage I and II cancers are

generally considered "early stage" cancers, <sup>18</sup> while Stage IV cancer is late-stage cancer. 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)). For this reason, asymptomatic screening tests are designed to identify cancer among "asymptomatic individuals who do not have a diagnosis of cancer" so that cancer can be detected at earlier stages. (RPFF ¶ 320); *see also* (Abrams Tr. 3620 ("Screening actually implies an asymptomatic person.")); {

Respondents claim that Galleri can detect more than 50 types of cancers, but this claim conflates Galleri's ability to detect cancer signals in previously diagnosed cancer patients (including many with Stage IV cancer) with the clinically relevant ability to detect cancer at *early stages* in an asymptomatic screening population. <sup>19</sup> There is, quite simply, no clinical evidence that Galleri can provide early detection of more than 50 types of cancer in an asymptomatic population.

<sup>18</sup> Cancer is considered to be localized in Stages I-II. (PX0086 at 001 (Grail Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "localized" cancers as "stage I-II")). Grail's own expert, Dr. Cote, said only Stage I and Stage II cancers were "early stage" cancers. *See* (RPFF ¶¶ 89-90). Grail has described Stage III cancer as an "early stage" of cancer in reporting study results, *see* (CCFF ¶ 6219), but an internal Grail document {

<sup>&</sup>lt;sup>19</sup> It would be natural for one to infer that Grail's claim of "detecting 50 cancers" must mean that Galleri can detect 50 types of cancer early in asymptomatic individuals (as Galleri is, after all, a multicancer early detection test intended for use in asymptomatic individuals). Such an inference might indeed be beneficial to Grail. But such an inference would be incorrect. Grail is generally very careful not to state publicly that the Galleri test provides "early detection" of 50 cancers or that Galleri has been shown to "screen" for 50 cancers in "asymptomatic" patients. Respondents' counsel, however, is less careful. *See* Resp. Post-Tr. Br. at 2 (claiming that Galleri "has demonstrated it can simultaneously screen for more than 50 types of cancer in asymptomatic patients") (emphasis added).

Rather, despite Respondents' claims, Galleri has been clinically shown to detect only *seven* types of Stage I through Stage III cancer in an asymptomatic screening population—a fact conceded by Respondents' own expert:

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.

(Cote Tr. 4000-01); see generally (CCFF ¶ 6206-394). The fact that Galleri can detect certain cancers once those cancers reach Stage IV is irrelevant to whether Galleri can detect those cancers early, or help save lives from cancer, as MCED tests aim to do. See (Ofman (Grail) Tr. 3430-31) (conceding that early detection of cancer means detecting cancer at earlier stages and that detecting Stage IV cancer is not an instance of early cancer detection). Moreover, the ability of a screening test to detect cancers once they reach Stage IV is mostly irrelevant, as at that stage those cancers "are likely detectable by symptoms." (PX4178 (Grail) at 024 (Email from S. Alag, Grail, to A. Chen, Grail, attaching "ILMN – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 12, 2020)); (RPFF ¶ 90) (citing Respondents' own expert, Dr. Cote, for the proposition that "cancer generally does not cause symptoms" at Stages I-II, and that "[b]y the time symptoms develop, the cancer has very often progressed to Stages III or IV"). It is far more difficult to detect early-stage cancer than late-stage cancer given the low level of cancer signal circulating in the blood. <sup>20</sup>

<sup>&</sup>lt;sup>20</sup> Respondents acknowledge as much in their own proposed findings of fact. See (RPFF ¶ 57) (stating that a "core problem in detecting cancer early in asymptomatic individuals" is "the low level of cancer signal circulating in the blood"); (RPFF ¶ 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 . . . ."); (RPFF ¶ 172.2) ("Compared with therapy selection tests where the patient has developed tumors, early stage cancer patients

Respondents point to two studies to support Galleri's capabilities, CCGA and PATHFINDER. Resp. Post-Tr. Br. at 48-50. Grail's CCGA study was broken up into three substudies: CCGA-1, CCGA-2, and CCGA-3. Respondents cite published results from both the CCGA-2 and CCGA-3 substudies, <sup>21</sup> but both were case-control studies that did not involve a realworld population. See (CCFF ¶¶ 6238-41). Accordingly, neither study establishes Galleri's specificity, sensitivity, positive predictive value, or the number of cancers Galleri can detect early in an asymptomatic population.<sup>22</sup> Grail's Chief Medical Officer, Dr. Ofman, conceded at trial that the CCGA study did not involve the intended use population for Galleri—asymptomatic patients. See (Ofman (Grail) Tr. 3294-95). Indeed, the authors of CCGA-3 explicitly caution 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, 32 Annals of Oncology 1167 (2021))). The authors of CCGA-2 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 010 (M. C. Liu et al., Sensitive and Specific Multi-

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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.").

<sup>&</sup>lt;sup>21</sup> CCGA-2 was conducted using "Version 1 of Galleri," and CCGA-3 was conducted using "Version 2" of Galleri. See (PX7092 (Ofman (Grail) Dep. at 251-52)). Version 2 of Galleri is the version Grail has commercialized. See (Ofman (Grail) Tr. 3303). Grail published selected results from its CCGA-2 substudy in 2020. (RX3430 (M. C. Liu et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 31 ANNALS OF ONCOLOGY 745 (2020))). Grail published selected results from its CCGA-3 substudy in 2021. (RX3409 (E. A. Klein et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 32 ANNALS OF ONCOLOGY 1167 (2021))).

<sup>&</sup>lt;sup>22</sup> 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 ¶¶ 6238-41).

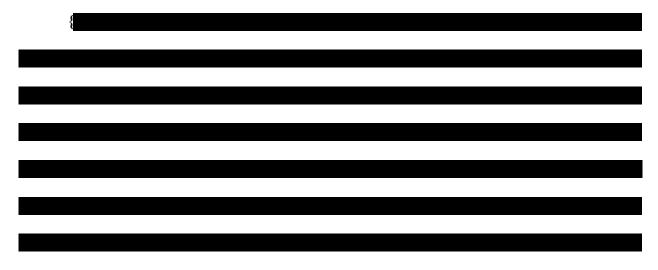
Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 31 Annals of Oncology 745 (2020))).<sup>23</sup>

Over 70 percent of participants in the cancer arm of the CCGA-2 and CCGA-3 substudies were identified by "clinical presentation," meaning participants were symptomatic for cancer prior to taking the Galleri test. *See* (CCFF ¶ 6244-45). 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 (who generally would not have been symptomatic prior to taking the Galleri test). (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*, 32 ANNALS OF ONCOLOGY 1167 (2021) (stating that "overall sensitivity" was 63.9 percent for cancers identified by "clinical presentation," versus just 18 percent for cancers identified by "screening tests"))). In other words, CCGA was strongly weighted towards individuals who had already presented with symptoms of cancer, even though Galleri is intended to screen for patients in an asymptomatic population.<sup>24</sup> Galleri's ability to tell people they have cancer *after* they have already presented with symptoms of cancer is not clinically significant.<sup>25</sup>

<sup>&</sup>lt;sup>23</sup> 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 of the CCGA-3 substudy note "could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." (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*, 32 ANNALS OF ONCOLOGY 1167 (2021))).

<sup>&</sup>lt;sup>24</sup> See (CCFF ¶¶ 6237-43, 6259). Galleri performed far worse at detecting cancer in individuals who are not yet symptomatic, but that poor performance was blended together with Galleri's 3x success rate from the 70 percent of participants diagnosed through "clinical presentation" in the published results from CCGA-3, thereby biasing the reported sensitivity results upwards. See (CCFF ¶¶ 6243-58).

<sup>&</sup>lt;sup>25</sup> Respondents' own proposed findings of fact bear this out. *See* (RPFF ¶¶ 318-18.1) (stating that "FDA is likely to only consider results from well-controlled clinical studies . . . that will demonstrate that the test 'will provide clinically significant results'" and that, therefore, "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.").



\$\}^{26}\$ 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 \\$\P\$\\$ 319-20).

Second, Respondents argue that Grail's PATHFINDER study,<sup>27</sup> for which only interim results have been released, demonstrates Galleri's ability to detect "13 different types of cancer at early stages." Resp. Post-Tr. Br. at 49 (citing Ofman (Grail) Tr. 3297-98 (as quoted in RPFF ¶ 398.3)). This is flatly untrue, and Respondents misstate Dr. Ofman's testimony. Dr. Ofman did not testify that Galleri detected "13 different types of cancer at early stages" in PATHFINDER. Rather, he testified that Galleri detected "13 different types of cancer, and some in their early stages." (Ofman (Grail) Tr. 3297-98 (emphasis added)). Dr. Ofman acknowledged: "To find . . .

<sup>26 {</sup> 

<sup>&</sup>lt;sup>27</sup> Unlike CCGA, PATHFINDER is an interventional study involving asymptomatic participants. *See* (CCFF ¶¶ 6283-84).

all 50 cancers . . . in a real-world population is going to require hundreds of thousands of people, so 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. (RX3041 at 005 (Tomasz M. Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021) [hereinafter "Interim Results of Pathfinder"] (showing seven cancers as being detected in stages one through three: 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—more than Galleri. See (RX3419 at 006-07, Table 1 (Anne Marie Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, 369 SCIENCE 369, 49 (2020))). In short, Grail's generic claim that Galleri can "detect 50 cancers" is not relevant to MCED testing because it has not been shown to detect 50 cancers in a screening setting in asymptomatic patients, which is what an MCED test is designed to do.

(ii) <u>Galleri's Cancer Signal of Origin ("CSO")<sup>28</sup> Performance Has</u> <u>Not Been Clinically Established in a Screening Setting</u>

Respondents also argue that only Galleri has "the ability to detect cancer signal of origin." *See, e.g.*, Resp. Post-Tr. Br. at 43. But reliable clinical data does not exist about how Grail's cancer

<sup>&</sup>lt;sup>28</sup> Grail described its algorithmic cancer localization classifier as a "tissue of origin" ("TOO") prediction for v1 of Galleri. Grail made certain changes to its algorithmic cancer localization classifier feature in v2 of Galleri and changed the name of the classifier to "cancer signal of origin" ("CSO"). The CCGA-2 substudy results and interim PATHFINDER results are for v1 of Galleri (and thus reflect Galleri's "TOO" classifier). The CCGA-3 substudy uses v2 of Galleri (and reflects Galleri's "CSO" classifier). Grail commercialized v2 of Galleri as an LDT (this version of Galleri uses the "CSO" classifier specifically). Respondents use both terms generically in their brief to refer to algorithmic cancer localization, and both terms were used relatively interchangeably by witnesses at trial. Both TOO and CSO are the same basic type of classifier—an algorithmic cancer localization classifier that attempts to predict the location of cancer from the liquid biopsy. When referring to results from specific studies, the specific name for

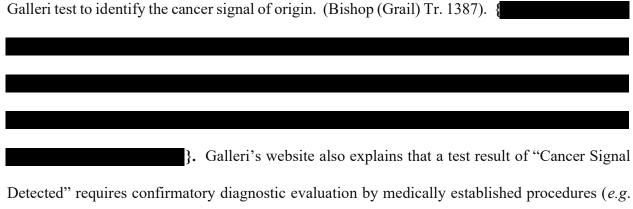
signal of origin feature would perform in an asymptomatic screening population. As explained *supra*, the CCGA study did not involve a real-world population, but rather was a case-control study with individuals who had already been diagnosed with cancer. The CSO accuracy numbers reported in CCGA do not 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*. Additionally, Galleri patients will require additional diagnostic testing to identify the location of cancer, including, in many cases, See generally (CCFF ¶¶ 3565-69). Indeed, Grail's former CEO, Hans Bishop, admitted at trial that certain patients may have to undergo a body scan following a positive

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the classifier from that study is used. More generally, deference is given to the terminology in the record, and so the terms are used largely interchangeably. (For a description of the specific changes made to the Galleri classifier between v1 and v2 of Galleri, see RX3409 at 003-004 (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]).

<sup>&</sup>lt;sup>29</sup> Specifically, the denominator for Galleri's reported CSO accuracy in CCGA was artificially limited to just those cases in which the original cancer prediction was correct (excluding false positives). (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*, 9 Annals of Oncology 1167 (2021) [CCGA-3]) (stating that the "overall accuracy of CSO prediction" statistics were calculated only among "true positives."). Obviously, however, a CSO prediction is not "correct" or "accurate" when a particular CSO category is predicted and the individual has no cancer at all.

<sup>&</sup>lt;sup>30</sup> Galleri's CSO classifier includes 20 cancer categories, not 50+. The eighth most common CSO category, by number of predictions in CCGA-3, was "Neuroendocrine Cells of Lung or Other Organs." (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) [CCGA-3]). This CSO "category" 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 031, 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" prediction is thus not actually a specific tissue of origin prediction at all. The CCGA-3 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)).

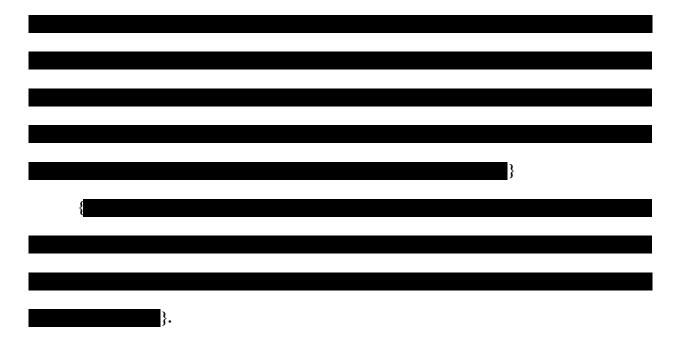


Detected" requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer. (PX0063 at 002 (Grail, Galleri Multi-Cancer Early Detection Test, https://grail.com/galleri/ (last visited Apr. 29, 2021))).

Moreover, Grail undertook the PATHFINDER study to assess the extent and types of follow-on diagnostic testing that will be required following a positive Galleri result and tissue of origin 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

origin 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."). Interim results from PATHFINDER indicate that additional imaging testing was required 90 percent of the time. (RX3041 at 003 (Tomasz M. Beer, Interim Results of Pathfinder, A Clinical Use Study Using Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting, 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 percent) and 25 percent of participants who received falsely positive results underwent at least one invasive procedure. (RX3041 at 003 (Tomasz M. Beer, Interim Results of Pathfinder, A Clinical Use Study Using Methylation-Based Multi-Cancer Early Detection Test,

2021 ASCO Annual Meeting, June 4, 2021)). {
}
It is not known today whether algorithmic tissue of origin prediction will ultimately prov
superior to other methods of identifying the location of cancer as part of MCED testing, such a
PET-CT. <sup>32</sup> {
32.4
32 {
}
49



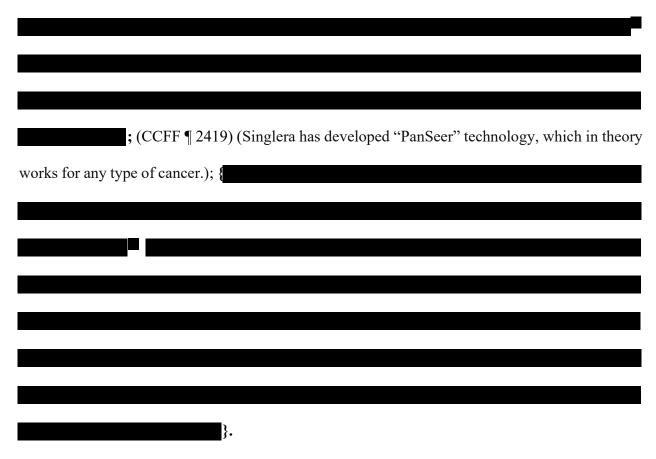
As Respondents' executives and expert admit, the purpose of MCED tests is to identify cancer in its early state in people who do not know they have cancer (*i.e.*, asymptomatic undiagnosed individuals). Respondents' generic claim that Galleri can detect 50 cancers is nothing more than a smokescreen designed to obfuscate the similarity between the Galleri and its rivals. Looking behind the screen instead reveals that Galleri has only been shown to detect for seven cancers in an asymptomatic population. Similarly, Galleri's clinical trials have not established that it can detect TOO across 50 cancers in an asymptomatic population or that an algorithmic approach is a superior approach to its rivals. A clear-eyed comparison of Galleri's actual attributes instead reveals that it shares much in common with its rivals.

b) Galleri Is Reasonably Interchangeable With CancerSEEK, Lunar-2, and Other MCED Tests in Development

Viewing Galleri through the lens of "market realities" rather than simply Grail's marketing makes clear that Galleri shares key functionality with other MCED tests in development. As an initial matter, all MCEDs are intended to detect cancer in asymptomatic patients by looking for

unique biomarkers in patients' blood. CC Post-Tr. Br. at 18-23. More specifically, though, the record shows that MCED test developers are all developing and commercializing tests intended to detect multiple cancers as well as to identify tissue of origin. As Complaint Counsel's post-trial brief explains, differences in how MCED test developers are getting to the end goal—the early detection of cancer—do not indicate that MCED test developers are in separate markets but rather are earmarks of competition. CC Post-Tr. Br. at 59-63.

MCED developers have discovered that a number of DNA mutations and methylation
biomarkers are actually common across many different cancers. See, e.g., (Bishop (Grail) Tr.
1375) ("the cancer signal, the abnormalities we're looking at are actually shared between many
different types of cancer"); {
}. Accordingly, each MCED test
developer has assembled a panel of biomarkers intended to detect a large number of early stage
cancers. See (CCFF ¶¶ 1938) (Exact/Thrive's CancerSEEK "is a test intended to detect all
types of cancers"); {



Galleri's rivals similarly plan on commercializing tests that detect multiple cancers.<sup>35</sup> For example, CancerSEEK has been shown in a prospective interventional clinical trial to detect eight

 $<sup>^{33}</sup>$  Dr. Chudova testified at trial that she is "focused on developing technology that could be used for detection of multiple cancer indications or precancer indications, any cancer." (CCFF ¶ 2277). Guardant's business strategy involves first creating a colorectal cancer ("CRC") test that will be rapidly adopted, then moving to a multi-cancer phase. (CCFF ¶ 2279).

<sup>}; (</sup>RX2770 (H. Yimer et al., Detection of Cancer Signal for over 50 AJCC Cancer Types with Multi-Cancer Early Detection Test, 2021 ASCO CCGA Poster, June 4-8, 2021); see also (CCFF ¶¶ 6206-6394) (presenting evidence that Galleri has not been clinically shown to provide early detection of more than 50 cancers in an asymptomatic population).

<sup>&</sup>lt;sup>35</sup> As Complaint Counsel's post-trial brief explains in full, while some MCED test developers are initially going to market with a single-cancer test, the record evidence is clear that they are not stopping their development at 1, 2, or even 3 cancers, but intend to continue expanding their cancer detection abilities to compete with Galleri. CC Post-Tr. Br. at 59-63.

cancers in an asymptomatic screening population—more than Galleri—in a study that even
Illumina has characterized as a "very carefully designed study in many ways" that could
"accelerate the Thrive test approval process and uptake as it is very defined." (CCFF $\P\P$ 2056-
2057); see also (CCFF ¶¶ 2016-60). Many MCED test developers have development plans to
study multiple cancers with the goal of expanding their product offerings to compete with
Galleri. {
<b>}</b> .
Despite Respondents' claims that Galleri is unique in its TOO capabilities (and despite the
fact that Respondents substantially overstate these claims), evidence also shows that other MCED
test developers are also developing algorithm tissue of origin tests. {
}; (CCFF ¶ 2426) (The PanSeer test is

also designed to detect tissue of origin.). As such, the evidence shows that Galleri is not unique in developing the ability to identify tissue of origin.

c) MCED Tests' Differentiated Features Are Facets of Competition

Contrary to Respondents' assertions, products need not be identical to fall within the same relevant product market. See United States v. Energy Sols., Inc., 265 F. Supp. 3d 415, 436 (D. Del. 2017) (products comprising a relevant market "need not be identical, only reasonable substitutes"). As explained in Complaint Counsel's post-trial brief, the number and types of cancers detected, level of sensitivity and specificity for different cancers, as well as the ability or inability to detect tissue of origin are all earmarks of competition. CC Post-Tr. Br. at 59-63. Respondents' arguments to the contrary in their post-trial brief are unavailing. Resp. Post-Tr. Br. at 47-50. In addition to an inflated characterization of Galleri's capabilities, Respondents' assertion rests on the contention "[m]ost of the tests in development are too underdeveloped to permit a meaningful comparison of their features," except for CancerSEEK and PanSeer. Resp. Post-Tr. Br. at 47. As explained extensively in Complaint Counsel's post-trial brief, MCED tests share similar features and are sufficiently developed for MCED test developers to recognize, track, and compete with their rivals. See CC Post-Tr. Br. at 18-23, 104-16. Moreover, Respondents' witnesses, MCED test developers, and ordinary course documents instead show that Grail (and its rivals) view these product features as facets of competition in this market, rather than a lack of competition. For example, {

} (CCFF ¶ 3281). Likewise,

both Respondents' witnesses as well as MCED test developer witnesses explain that they expect

to compete on the number of cancers detected. See (
(PX7062 (Kollu (Grail) IHT at 130-131) (explaining that one of the bases of competition will be "that one technology may look for a certain number of
cancers vs others");
Witness testimony is also bolstered by an assessment of the types of cancers MCED test
developers are prioritizing for commercialization: the deadliest and/or the most common cancer
types. For example, {
3. Collectively, these account for over 50
percent of new cancer cases in 2019, including the three most common cancers lung, breast, and
colon cancer. See (RX3030 at 006 (ACS) 2019 Facts and Figures). { prioritized
cancers including two of the three leading causes of cancer-related death in men and the top three
causes of cancer-related death in women. (RX3030 at 006 (ACS) 2019 Facts and Figures).
Similarly,
} (CCFF ¶ 2312).
} of all new cancer cases in 2019,
including the three most common cancers. (RX3030 at 006 (ACS) 2019 Facts and Figures).
Similarly, {

RX3030 at 006 (ACS) 2019 Facts and Figures). For some patients and clinicians,

For example, Galleri has only been shown to detect Stage I-III prostate cancer with 5.7 percent sensitivity. (CCFF ¶ 6371). Certain men might choose a MCED test that screens for fewer cancers but is better able to detect prostate cancer, illustrating the consumer benefits of having

multiple choices for MCED tests.

Respondents likewise argue that "differences between the specificity and sensitivity of the tests" as well as the positive predictive value (PPV) between Galleri and its rivals mean Galleri will face no competition from its rivals. Resp. Post-Tr. Br. at 47-48. As with TOO and the number of cancers, Grail cannot say today what the sensitivity, specificity, or PPV of Galleri will be in Galleri's intended use population (*i.e.* in an asymptomatic screening population) given 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)). {

Given the skewed nature of CCGA3 study, the CEO of Exact, Kevin Conroy, explained that any comparison of Galleri's sensitivity to the results of Exact's prospective study is not an accurate comparison. (CCFF ¶¶ 2090-2093). Moreover, MCED test developers are continuing to improve their tests and expect such features such as sensitivity, specificity, or PPV

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to be a facet of competition in the research, development, and commercialization of MCED tests. (CCFF  $\P\P$  2053-58,  $\P\P$ ),  $\P$ ).

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An accurate comparison shows that MCED test developers are all in the process of developing tests that share the same core features. Respondents' claims—even if they were true—are irrelevant because the record evidence shows that 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.

36 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).

The evidence as a whole proves that MCED test developers are each developing an MCED test designed to compete with Galleri and with one another across a multitude of functions. Aside from being manufactured or exaggerated, the "differences" among the MCED tests in development do not indicate that they are in different markets than Galleri, but rather show facets of competition. *Staples*, 190 F. Supp. 3d at 117 ("In other words, a product market includes all goods that are reasonable substitutes, even where the products are not entirely the same."); (PX7132 (Willig Dep. at 84) (explaining that "products can compete on the basis of differentiated features")).

#### iii. Unique Production Facilities

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.").

#### iv. Distinct Customers

When applying the *Brown Shoe* factor of "distinct customers," Respondents continue their trend of inflating the difference between Galleri and other MCED tests, arguing that Galleri will target a different customer set than its competitors. Resp. Post-Tr. Br. at 57. As already explained

#### v. Distinct Prices and Sensitivity to Price Changes

Respondents allege that the "quantitative inquiry here starts and ends with Galleri" because "Galleri is the only MCED test with a price." Resp. Post-Tr. Br. at 58. 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."). Here, the evidence shows that MCED test developers are already developing pricing strategies. For example, Exact has plans to sell its MCED for {

| Grail's ordinary course documents also show that {
| For example, in assessing the competitive threat of its rivals, Grail noted that {

Furthermore, MCED test developers testified that they expect to compete with Galleri on price. (CCFF ¶¶ 698-704). 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). Moreover, Respondents' own documents show expected price competition among MCED test developers. {

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. Here, Respondents' ordinary course documents and the market realities show

Respondents argue that Complaint Counsel does not appropriately consider the effect of payer adoption and clinical utility on how MCED tests will be priced. Resp. Post-Tr. Br. at 59. In contrast, Dr. Scott Morton explained that this . (PX6091 (Scott Morton Rebuttal Report) ¶ 63). While Respondents want to characterize this as "speculative," Dr. Scott Morton's analysis is supported by well-established legal and economic principles. See, e.g., ProMedica Health System, Inc. v. FTC, 749 F.3d 559, 571-72 (6th Cir. 2014) (holding that a merger could violate the Clayton Act despite the fact that insurers impacted market dynamics).

that Galleri and other MCED tests will compete with each other on price and other factors. *See, e.g.*, (CCFF ¶¶ 698-704).

#### vi. Specialized Vendors

Respondents argue that MCED test developers use different vendors because some MCED test developers may use a single blood draw to detect cancer and identify TOO, whereas others may include a PET-CT scan to identify tissue of origin. Resp. Post-Tr. Br. 62. First, Respondents' allegation mischaracterizes the evidence. An analysis of Galleri's clinical trial data shows that Galleri has yet to clinically validate its ability to detect TOO for all cancer types in an asymptomatic screening population. *See*, *supra*, § I.B.2.b.ii.a(ii). Even assuming that Galleri will test for TOO, 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). Grail's ordinary course documents similarly show that its tissue of origin feature {

| Moreover, other MCED tests are also developing tissue-of-origin capabilities. {
| As such, the weight of the evidence shows that Galleri and the other MCED test developers will all use similar vendors for both the initial blood draw and any subsequent diagnostic imaging.

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When applying the *Brown Shoe* practical indicia, Courts pay "close attention to the defendants' ordinary course of business documents." *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017) (quoting *H&R Block*, 833 F. Supp. 2d at 52). Here, an application of the *Brown Shoe* factors guided by the "realities of competition" reflected by both MCED test

developer testimony as well as the ordinary course documents show that Galleri shares key features with the other MCED tests in development, and MCED test developers including Grail are competing today in the market for the research, development and commercialization of MCED tests. *H&R Block*, 833 F. Supp. 2d at 52 (explaining that the Court pays "close attention to the defendants ordinary course business documents" in assessing market definition); *see also Staples*, 190 F. Supp. 3d at 124 (assessing the "commercial realities" reflecting competition between market participants, which supported the Government's relevant product market definition);

## C. Expert Economic Analysis Also Supports the Market for the Research, Development, and Commercialization of MCED Tests

In addition to the *Brown Shoe* practical indicia, courts also find expert economic analysis of the proposed market probative. *See Sysco Corp.*, 113 F. Supp. 3d at 37. Complaint Counsel's expert—Dr. Scott Morton—testified that the MCED market is the relevant product market. (PX6090 (Scott Morton Report) ¶¶ 140-149) (*in camera*); (PX7138 (Scott Morton Trial Dep. at 39-40) (*in camera*)). Respondents ask this Court to disregard Dr. Scott Morton's testimony because they allege it is

Resp. Post-Tr. Br. at 65-66. As an initial matter, Dr. Scott Morton analyzed the

See, e.g., (PX6090 (Scott

Morton Report) ¶¶ 141-146, 179-173 (in camera)). The fact that she did not examine data describing past purchase patterns of consumers and their responses to price changes does not

impact the probative value of her expert opinion.<sup>38</sup> 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.

Respondents also misquote Dr. Scott Morton saying that she improperly weighed the evidence in violation of the province of an expert witness. (PX7138 (Scott Morton Trial Dep. at 194) (*in camera*)). As Dr. Scott Morton explained,

(PX7138 (Scott Morton Trial Dep. at

194-95 (in camera)) {

<sup>&</sup>lt;sup>38</sup> Respondents' argument regarding payer adoption is similarly unavailing. As Dr. Scott Morton explains, she properly analyzed the pricing competition between MCED tests that would impact payer acceptance. *See, e.g.*, (PX6091 (Scott Morton Rebuttal Report)  $\P$  63).

} 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.<sup>39</sup>

Nonetheless, Respondents argue that Dr. Scott Morton erred in applying her SSNIP test to the wrong set of products by focusing only on the question of whether MCED tests are substitutes for therapy selection, MRD, and single-cancer tests. Respondents mischaracterize Dr. Scott Morton's analysis. To the contrary, Dr. Scott Morton analyzed extensively the characteristics of Galleri and its MCED test competitors. (PX6090 (Scott Morton Report) ¶¶ 85-126) (*in camera*). Dr. Scott Morton's analysis corroborates the testimony of MCED test developers and Respondents' own documents, and shows that a hypothetical monopolist of all MCED products would likely be able to profitably impose a SSNIP above the MCED price that would prevail if there were multiple MCED rivals, or profitably implement a significant reduction in product quality or availability. *See, e.g.*, (PX6090 (Scott Morton Report) ¶ 149) (*in camera*).

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<sup>&</sup>lt;sup>39</sup> 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). In contrast, here, Dr. Scott Morton's testimony is supported by robust record evidence as explained throughout her expert reports. *See generally* (PX6090 (Scott Morton Report)); (PX6091 (Scott Morton Rebuttal Report)).

Moreover, to the extent that Respondents are arguing that there exist additional, narrower markets that could also be defined, it is of no import. Drawing a narrower market that includes only the Galleri test—as Respondents appear to be arguing—would fail to identify the full set of products where competitive harms are likely to be manifested in contravention of the purpose of market definition. (PX6091 (Scott Morton Rebuttal Report) ¶ 65) (in camera).

# D. Complaint Counsel's Relevant Market Is Supported by Legal Precedent and Economic Theory

While Respondents' exact argument is unclear, they appear to contend that (1) Complaint Counsel relies only on "platitudes" about innovation in support of its market definition instead of "analysis grounded in law and fact"; (2) defining a market comprising innovation harm is inconsistent with FTC policy from 1995; and (3) defining a market around innovation will lead to too many false positives. Resp. Post-Tr. Br. at 70-72. Respondents' arguments are meritless.

Throughout its post-trial briefing, Complaint Counsel has grounded its market definition analysis in well-established, long-standing precedent supported by citations to a robust factual record. CC Post-Tr. Br. at 49-59; see also supra § I.A. As noted elsewhere, 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 there 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. Respondents cite inapposite district court Section 2 cases that have no bearing on the appropriate standard for defining a market in a Section 7 case. As an example, Respondents confusingly cite *OrthoAccel Techs. Inc. v. Propel Orthodontics*, which explains that even under the higher Section 2 standard a product market can be sufficiently pleaded in a nascent market by showing reasonable interchangeability—as Complaint Counsel has done here. No. 4:16-CV-00350, 2017 WL 1213629, \*4 (E.D. Tex., Apr. 3, 2017) ("Propel's counterclaims allege facts, which the Court must accept as true, that plausibly show the VPro5 is reasonably interchangeable with the AcceleDent device.").

Respondents also argue that Complaint Counsel's market definition is based on "subjective and changing policy assessments" and that Complaint Counsel cannot rely on innovation principles in defining a market because "[i]nnovation is intangible, uncertain, unmeasurable" and "[t]he potential harm from these false positives is especially great where, as here, there is unrefuted evidence that the Transaction will save lives." Resp. Post-Tr. Br. at 71 (internal citations omitted). Respondents' reliance on policy statements and economics analysis from 1995 is misplaced. As modern economic theory recognizes—including Respondents own experts—innovation has competitive benefits that inure to consumers. (PX7132 (Willig (Illumina) Dep. at 117-18)

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<sup>&</sup>lt;sup>40</sup> Complaint Counsel has explained previously that Respondents' arguments that rely upon *Apartment Source* and *Epic Games* are inapposite. *See, supra*, § I.A.1 & n.8. *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.*, 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 the reasonable interchangeability of Galleri and its MCED rivals. *See supra* § I.B.

(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.")). 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.<sup>41</sup>

Respondents contend that defining 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

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<sup>&</sup>lt;sup>41</sup> Respondents assert that Dr. Scott Morton should have performed a different market definition analysis to properly define an innovation market. Resp. Post-Tr. Br. at 72 ("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?"). 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). This Court explicitly required Dr. Katz to stay within the bounds of Dr. Willig's report when allowing Respondents to substitute his testimony for Dr. Willig's. *See* Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness at 4. Given that Dr. Willig offered no opinion regarding the requirements for defining an innovation market, Dr. Katz's testimony regarding this topic violates this Court's Order and should be disregarded. (RX3871 (Willig Report) ¶¶ 6-8).

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)).

## II. Overwhelming Evidence Shows That Illumina's NGS Platforms Are Related Products to MCED Tests

# A. Respondents' Claim That Complaint Counsel Must Prove a "Related Product Market" Is Baseless and Unsupported by Caselaw

Complaint Counsel alleged that Illumina's NGS platforms are related products to MCED tests, and overwhelming evidence showed that they are a critical inputs for MCED test developers to research, develop, and commercialize their MCED tests. CC Post-Tr. Br. § II.D; (CCFF ¶¶ 886-1211). But Respondents wrongly inform this Court that "Complaint Counsel was required to prove a related product market to prevail." Resp. Post-Tr. Br. at 72. Respondents' contention has no basis in the statutory language of the Clayton Act, the extensive caselaw applying Section 7, or in economic theory. Rather, under longstanding court precedent, Complaint Counsel is required only to identify a related product through which Illumina would have the ability to harm Grail's rivals. See, e.g., Ford Motor Co. v. United States, 405 U.S. 562 (1972); Brown Shoe, 370 U.S. 294, United States v. E.I. du Pont de Nemours & Co., 353 U.S. 586 (1957); Steves & Sons, Inc. v. JELD-WEN, Inc., 988 F.3d 690 (4th Cir. 2021); United States v. AT&T, Inc., 916 F.3d 1029 (D.C. Cir. 2019). Complaint Counsel has far surpassed this requirement, showing that not only do Grail's rivals rely on Illumina's NGS platforms, but that Illumina's NGS platforms are a *necessary* input for Grail's rivals. See CC Post-Tr. Br. § II.D. Rather than base their arguments in the law, Respondents ask this Court to impose a novel requirement and "infer" that defining a related product market is a

legal element, Resp. Post-Tr. Br. at 74, albeit one that has never been required in the seven decades since Section 7 was amended to cover vertical mergers and has no basis in modern economic theory.<sup>42</sup>

Respondents fail to identify any statutory authority that requires Complaint Counsel to define a related product market because no such authority exists. The longstanding requirement for defining a relevant product market is grounded in the language of Section 7 of the Clayton Act, which 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 (emphasis added). The explicit statutory requirement that the substantial lessening of competition occur in a "line of commerce" is the basis for the relevant product market element. *Brown Shoe*, 370 U.S. at 324; *du Pont*, 353 U.S. at 593-94. In contrast, the clear statutory language omits any such reference to an upstream line of commerce. Respondents cannot point to any such statutory basis for their claim of a related product market element, for none exists.

In addition to the lack of statutory authority for Respondents' claims, no court has ever required a plaintiff to define a "related product market" in a Section 7 challenge to a vertical

<sup>&</sup>lt;sup>42</sup> Respondents later appear to contend that Complaint Counsel needs "to define a related market in which Illumina is a monopolist." Resp. Post-Tr. Br. at 76. Respondents cite to no caselaw or support for this even stricter contrived standard. Ultimately, though, Respondents miss the point as to why the related product matters. It is not an arbitrary line-drawing exercise. Rather, the analysis serves to assess how the Acquisition affects Illumina's ability and incentive to disadvantage Grail's rivals. *See* CC Post-Tr. Br. § II.E.1. A related product need not be a monopoly, as monopoly power is unnecessary for the Acquisition to change Illumina's incentives or for Illumina to have the ability to harm Grail's rivals. *Brown Shoe*, 370 U.S. at 302-05, 334 (finding substantial lessening of competition where a vertical merger foreclosed 1.2 percent of the market); Steven C. Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale L.J. 1962, 1973 (2018) ("An upstream merging firm that is not an unregulated monopolist protected by prohibitive entry barriers has a similar intrinsic incentive to engage in input foreclosure by raising the input price it charges to the rivals of its downstream merger partner.").

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"). Respondents misleadingly cite only two cases to support their novel position. A cursory look quickly reveals that neither case supports Respondents' proposition.

Respondents first misleadingly cite to *Fruehauf Corp. v. FTC*, 603 F.2d 345 (2d Cir. 1979), as an example of a vertical merger case that shows the need for proving related product market. Resp. Post-Tr. Br. at 74. *Fruehauf* concerned the acquisition of a manufacturer of heavy duty wheels ("HDWs") and antiskid braking devices ("ASBDs") by a manufacturer of truck trailers. *Fruehauf*, 603 F.2d at 348. 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, 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.

<sup>&</sup>lt;sup>43</sup> Even Respondents are forced to admit that no court has ever expressly stated that a related product market is a requirement for a vertical merger challenge under Section 7, and instead ask this Court to *infer* the requirement based solely on an incomplete and misleading summary of *Fruehauf*. Resp. Post-Tr. Br. at 74.

Respondents likewise find no support in AT&T. Misleadingly, Respondents 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. Resp. Post-Tr. Br. at 73. 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.

Because there is no vertical merger caselaw to point to for their unsupported claims, Respondents venture outside of Section 7 cases, instead choosing to cite to an assortment of Section 2 cases.<sup>44</sup> In doing so, Respondents ignore the purpose of the Clayton Act. One of Congress's justifications for amending the Clayton Act was "to arrest restraints of trade in their incipiency and before they develop into full-fledged restraints violative of the Sherman Act." Brown Shoe, 370 U.S. at 323 n.39 (quoting 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. Contrary to Congress's clear mandate and long-standing precedent, Respondents inexplicably quote a footnote from American Express stating 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 n.7 (2018). The rule of reason framework is not applicable to merger challenges under Section 7 of the Clayton Act.

<sup>&</sup>lt;sup>44</sup> In addition to a plethora of Section 2 cases, Respondents also cite to *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109 (D.D.C. 2004), an inapposite horizontal merger case that does not reference, in any conceivable way, a related product or related product market. Resp. Post-Tr. Br. at 73 (citing *Arch Coal*, 329 F. Supp. 2d at 116).

Moreover, the passage again refers to defining the market where an anticompetitive effect is alleged.

Respondents further endorse commentary on the Vertical Merger Guidelines<sup>45</sup> from Dr. Scott Morton, along with other economists, arguing that it "supports the necessity of defining a related product market, especially in cases of alleged input foreclosure such as this one." Resp. Post-Tr. Br. at 74-75. This commentary, however, 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. The authors instead recommend an analysis focused on the role of the related product on a merger's competitive effects, *see id.*, the exact same analysis that Complaint Counsel conducted here. CC Post-Tr. Br. § II.E; *see also* (PX7138 (Scott Morton Trial Dep. at 54-59) (*in camera*)). 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)).

<sup>&</sup>lt;sup>45</sup> Respondents also misstate the prior Vertical Merger Guidelines, which were withdrawn by the FTC on September 15, 2021, as requiring a related product market. The Vertical Merger Guidelines provided only that in addition to identifying "one or more relevant markets in which the merger may substantially lessen competition," the Agencies will also "specify one or more related products." U.S. Dep't of Justice & Fed. Trade Comm'n, Vertical Merger Guidelines § 3 (2020). The Vertical Merger Guidelines explained a related product is "a product or service that is supplied or controlled by the merged firm and is positioned vertically or is complementary to the products and services in the relevant market." U.S. Dep't of Justice & Fed. Trade Comm'n., *Vertical Merger Guidelines* § 3. Complaint Counsel has specified the related product here.

# B. The Overwhelming Evidence Shows That Illumina Supplies a Related and Critical Input to MCED Test Developers

Respondents contend that 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" when analyzing Illumina's NGS platforms as related products to MCED tests. Resp. Post-Tr. Br. at 76. This is contradicted by the extensive record evidence, as detailed in Complaint Counsel's briefings, that outline the "nature, cost, usage, and other features" of NGS platforms and, specifically, MCED test developers' NGS platform requirements. CC Post-Tr. Br. 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. CC Post-Tr. Br. at 67-79; (CCFF ¶ 1053-1211).

#### 1. No Existing NGS Platform Other Than Illumina's Meets the Requirements for MCED Tests

Complaint Counsel has showed extensive evidence that Illumina's NGS platform is the only platform that satisfies the cost, accuracy, and throughput requirements for MCED tests. *See* CC Post-Tr. Br. § II.D.2; (CCFF ¶¶ 925-1018). Despite this direct countervailing evidence, Respondents claim that BGI,<sup>47</sup> Thermo Fisher, and Oxford Nanopore ("ONT") are other viable NGS platforms on the market that can support MCED tests in development. Resp. Post-Tr. Br. at 77-78. Rather than rely on any MCED test developers, though, Respondents' analysis is wholly

<sup>&</sup>lt;sup>46</sup> Respondents inexplicably cite to *Grason Electric* here—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).

<sup>&</sup>lt;sup>47</sup> Respondents' description of BGI as "a commercially available NGS platform" is grossly misleading. Respondents themselves admit that BGI's NGS platform is not commercially available in the United States. Resp. Post-Tr. Br. at 77 ("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."); Resp. Post-Tr. Br. at 125 (arguing that "BGI *will* enter the U.S. market" after certain Illumina patents expire in 2023) (emphasis added); *see also* (CCFF ¶¶ 1274-75).

dependent on their paid experts and documents that Respondents improperly attribute to BGI and ONT. *See, e.g.*, (Response to RPFF ¶ 778) (citing Dr. Cote's expert report to claim, contrary to all evidence, that Thermo Fisher's sequencers are { (Response to RPFF ¶¶ 587, 589, 591, 592, 598, 600.3) (misattributing sources of its findings as coming from BGI and ONT when this is not true). These unreliable sources run counter to the real-world facts facing every MCED test developer and supported by Respondents' own documents as well as other industry participants—that Illumina offers the only NGS platform that they can use for their MCED tests. *See, e.g.*, {

}; see also (CCFF ¶ 1053-1211).

The critical characteristics of an NGS platform for use in an MCED test are the cost, accuracy, and throughput of the platform. *See* CC Post-Tr. Br. § II.D.2; (CCFF ¶ 925-1018). As was explained at trial, for the application of MCED testing the key metric of an NGS instrument's throughput is the number of DNA fragment molecules that can be simultaneously read by the instrument during a run (reads per run). (CCFF ¶ 935-36, 940, 954, 981). The number of reads per run, in turn, determines how many MCED test patient samples can be processed on the NGS instrument during that run. (CCFF ¶ 118-19, 937, 941, 954). Respondents' attempts to compare the capabilities of other commercialized NGS platforms—namely BGI, Thermo Fisher, and ONT—to Illumina's platforms ignore MCED witness testimony and market realities and depend on a misleading measure of throughput that is irrelevant to the application of MCED testing.

}<sup>48</sup> But each

Throughout Respondents' post-trial brief, Respondents attempt to mislead the Court by comparing the throughput of NGS platforms using the inapplicable and misleading metric of gigabases per run, rather than the metric of reads per run. Gigabases per run refers to the total number of DNA bases sequenced and is calculated by multiplying the number of reads per run by the length of each read. (CCFF ¶ 934, 4681). The problem with this metric is that specifying only the total number of gigabases per run does not indicate *how* all that sequence was generated—for example, by sequencing many short DNA fragments, or by sequencing a few long DNA fragments, or something in between. A short-read sequencer that achieves 20 billion reads per run that are 100 bases long would have the same throughput in gigabases per run as a long-read sequencer that reads 20 million reads that are 100,000 bases long, even though the long-read sequencer reads 1,000 times fewer fragments.

This distinction matters. The application of MCED testing requires an instrument with the ability to sequence an extremely high number of DNA fragments (CCFF ¶ 937) because it is essentially looking for a "needle in a haystack"—i.e., one ctDNA molecule (from a cancer cell) present among every 10,000-100,000 cfDNA molecules (from normal cells). (CCFF ¶¶ 924, 1091). MCED tests must sequence tens of millions of DNA fragments per patient. (CCFF ¶ 4681); see also {

of those cfDNA fragments is short, as the average ctDNA fragment is less than 167 base pairs long. (CCFF ¶ 908). The proper NGS tool for this job, therefore, is an instrument capable of a

<sup>&</sup>lt;sup>48</sup> For example, if {

very high number of short reads per run, not an instrument capable of a low number of long reads per run. As Dr. Vogelstein of Johns Hopkins explained, long-read sequencing technologies "are not applicable to the analysis of plasma DNA... [T]he reason is simple to understand: Plasma DNA is not long." (CCFF ¶ 908).

Neither Respondents nor any of their witnesses could articulate why "gigabases per run" is a purportedly meaningful throughput metric for MCED tests, given that it does not convey the number of cfDNA molecules that can be sequenced.

see also (CCFF ¶ 1172) (Singlera's Gao testifying that Singlera requires an NGS platform that is economic in terms of reads per run). Rather, the appropriate metric for comparing NGS platforms is reads per run, i.e., how many individual DNA fragments a sequencer can read in a single run. Similarly, when comparing costs among sequencers, the relevant metric for the application of MCED testing is the cost per read (or per million reads), not the cost per gigabase, because cost per read is what drives the sequencing cost per patient sample. (CCFF ¶¶ 1118-25). Ignoring this critical distinction allows Respondents to deceptively present alternative NGS sequencers as options for MCED test developers (based on their gigabase per run throughputs) when they are not.

For example, Respondents

to ONT's and BGI's platforms. 49 Resp. Post-Tr. Br. at 80.

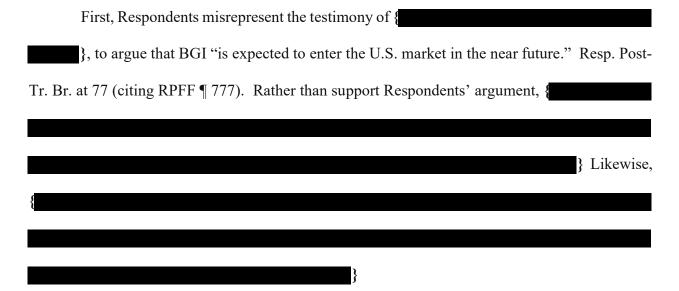
<sup>&</sup>lt;sup>49</sup> No evidence in the record provides any reliable information about the costs of BGI, *see* (Response to RPFF ¶¶ 594-594.2), and even if there were such evidence, BGI's platform is both immature and enjoined from being sold in the United States, and MCED test developers unanimously testified that it is not a viable option for their MCED tests. (CCFF ¶¶ 1287-95, 1308-19, 1325-45).

# a. BGI Is Not Commercially Available in the United States and Not an Alternative for MCED Tests

Respondents repeatedly tout BGI as a current possible alternative for MCED test developers in the United States. While Respondents admit that BGI is not commercially available in the United States today, for the rest of this year, or even in 2023, they argue that {

Respondents do not cite trial testimony from any BGI executives to support their contention because they did not call any BGI witnesses. Nor do Respondents quote any deposition testimony from BGI witnesses because Respondents did not subpoena anyone from BGI to testify. And

Respondents do not cite any BGI ordinary course documents because they did not subpoena any documents from BGI. Instead, Respondents rely on misrepresenting third party testimony about BGI to make three arguments: (1) that BGI is expected to enter the market in the near future; (2) that the only barrier to entry by BGI is an injunction for infringing patents that expire in 2023; and (3) that BGI has an NGS platform that is comparable to Illumina's NGS platform.



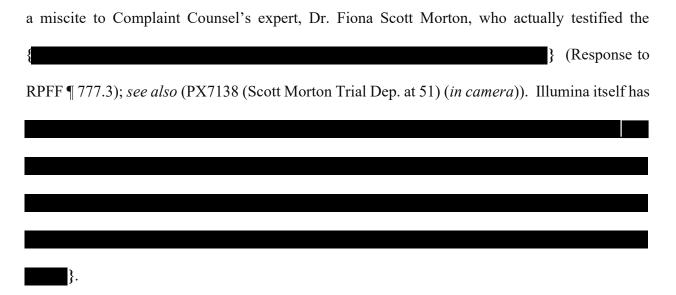
Second, Respondents imply that the only barrier to BGI entering the market is an injunction "due to its infringement of a certain Illumina patents that expire in 2022 and 2023." Resp. Post-Tr. Br. at 77. But Respondents fail to acknowledge that Illumina has filed additional patent infringement claims against BGI over patents that expire as late as December 22, 2027, (CCFF ¶¶ 1276-79), 50 and that Illumina has still further patents that it may enforce against BGI. (CCFF ¶¶

<sup>&</sup>lt;sup>50</sup> The jury rendered a verdict in favor of Complete Genomics on May 6, 2022. Redacted Jury Verdict, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (May 6, 2022). After receiving the verdict, Illumina informed the court that it plans to file two post-trial motions: a motion for judgment as a matter of law, and a motion for a new trial. *See* Post-Tr. Joint Status Rep., *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (May 13, 2022). Additionally, in a filing with the Securities and Exchange Commission, Illumina stated that it "disagrees with the jury's verdict and intends to vigorously defend the action, including filing all appropriate appeals." Illumina, SEC Form 8-K (May 6, 2022).

1284). As Illumina's Dr. Aravanis noted for investors, "[a]s we learn more about BGI's products, additional patents may become relevant," because Illumina has additional patents touching "every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics." (CCFF ¶ 1284). Respondents also ignore

}. (CCFF ¶ 1205). As the Supreme Court has recognized, even baseless intellectual property litigation can be a barrier to entry. *See Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993) (recognizing even sham intellectual property litigation as a barrier to entry). Likewise, MCED test developers recognize that this is a substantial barrier and testified that it is one of the many reasons that they do not view BGI as an option for their MCED tests. (CCFF ¶1286-95, 1573-75). Clearly here, where BGI is already enjoined from entering until 2023 and Illumina has filed additional claims seeking to enjoin BGI through 2027, entry is far from likely.

Respondents then proceed to argue that BGI has the performance capabilities necessary for MCED tests, brazenly claiming that "Complaint Counsel does not dispute that [BGI's NGS platform] is technically comparable to Illumina's NGS technology." Resp. Post-Tr. Br. at 77 (citing RPFF ¶ 777.3). On the contrary, Complaint Counsel has repeatedly and vigorously disputed that BGI's NGS platform is comparable to Illumina's NGS platform, and done so with extensive supporting evidence, including testimony from MCED test developers and Illumina's own documents and court filings. *See, e.g.*, CC Post-Tr. Br. at 136-38; CC Pre-Tr. Br. at 98-100; (CCFF ¶¶ 1267-1345); (Op. Stmt. (FTC) Tr. 21, 46-47). Respondents' purported support for this claim is



Respondents' claims about BGI's equivalence are also contradicted by testimony from multiple witnesses who have personal experience with BGI's technology and testified that it is inferior to Illumina—a conclusion that Illumina itself has embraced and successfully argued in other courts. For example, {

BGI's reputation for unreliability and poor service prevents Singlera from using BGI sequencers to run its PanSeer test. (CCFF ¶ 1342-43). Illumina itself told a federal court in February 2022 that BGI's NGS platform is "unproven and immature" and that "[i]t is simply inconceivable that [BGI's platform] is 'more accurate' than Illumina's industry leading systems." Pl.'s Reply in Support of Mot. for Permanent Inj. at 10, *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770 (N.D. Cal Feb. 16, 2022). The court agreed, finding that BGI's NGS platform is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co.*, No. 19-CV-03770-WHO, 2022 WL 899421, at \*25 (N.D. Cal. Mar. 27, 2022).

Moreover, MCED test developers have testified that they are reluctant to switch to BGI,
even if it became available, due to the uncertainty surrounding its freedom to operate in the United
States. (CCFF ¶¶ 1286-95). As {
And Respondents do not attempt to contradict testimony from MCED test developers
regarding their concerns about BGI's poor reputation, such as its involvement in human rights
abuses. (CCFF ¶¶ 1296-1324); see also FTC v. CCC Holdings Inc., 605 F. Supp. 2d 26, 54-55
(D.D.C. 2009) (holding that reputation is a "legitimate barrier[] to entry"). As {
These abuses put BGI's ability to operate in the United States at grave
risk. {
}

As Singlera's Dr. Gao explained, "We cannot risk our future on other companies' legal potential and commercial potential." (CCFF ¶ 1292). This is not a risk MCED test developers face if they use Illumina's NGS platform. In summary, Respondents have failed to show that entry by BGI would be timely or likely, as it is far from clear that BGI would enter even in 2023. More importantly, Respondents have not shown that entry by BGI would be sufficient for reasons related both to its lack of technical capabilities and high switching costs.

## b. Respondents Ignore Extensive Evidence Showing Thermo Fisher Is Not an Alternative for MCED Tests

The only non-Illumina short-read NGS platform on the market today is Thermo Fisher. But as Complaint Counsel proved at trial, it is not an option due to its low throughput, low accuracy, and high cost. CC Post-Tr. Br. § II.D.2.a; (CCFF ¶¶ 1212-1268). While Respondents stop short of a full-throated endorsement of Thermo Fisher's platforms as alternatives for MCED tests, they do argue that its "Ion Torrent sequencers are still suitable for certain [unspecified] multicancer screening tests." Resp. Post-Tr. Br. at 78. But even Respondents admit in their post-trial brief that { Resp. Post-Tr. Br. at 78. Evidence presented at trial (from MCED test developers and Thermo Fisher itself) unequivocally shows that Thermo Fisher is not an alternative for MCED test developers. { See, e.g., (CCFF ¶ 1237-42) (Freenome's head-to-head comparison of Thermo and Illumina showed Thermo's platform was incapable of meeting the requirements of its MCED }); (CCFF ¶¶ 1245-50) (Singlera Co-founder Gary Gao concluding that Thermo's platform was "not going to be a viable alternative" because it was less accurate, more expensive, and had a lower throughput than Illumina's platform); }. As Dr. Scott Morton explained, {

} (PX7138 (Scott Morton, Trial Dep. at 188-89) (in camera)). Instead of relying on this
direct evidence, Respondents' claims rest on the unreliable and improper opinion testimony of one
of their paid experts—Dr. Richard Cote—who is not qualified to offer opinion testimony about
which NGS platforms are viable for MCED testing. See (Response to RPFF ¶ 1968) {
Rather, as another Respondents' expert,
Dr. Willig, testified, {
<b>}</b> .
Perhaps most surprising, Respondents incorrectly state that {
} a
claim directly contradicted by trial and deposition testimony from Thermo's own executive Dr.
Andy Felton. <sup>51</sup> Resp. Post-Tr. Br. at 78 (citing RPFF ¶ 778.1); see also (Response to RPFF ¶
778.1). As Dr. Felton made clear, {
} (CCFF ¶¶ 1212-13, 1222). Dr. Felton further elaborated that even Thermo
Fisher's highest throughput sequencer, the GeneStudio, is not an option for MCED developers
because it is only capable of 130 million reads per run and "isn't well suited to a kind of test that

Fost-Tr. Br. at 78. This assertion is vague to the point of meaninglessness; a liquid biopsy test simply refers to a test that samples blood or other bodily fluids rather than tissue. (CCFF ¶¶ 271, 278). Although MCED tests are a type of liquid biopsy test, there are many others such as therapy selection tests, diagnostic aid to cancer tests, and residual disease tests, each with different requirements for sequencing instruments. (CCFF ¶¶ 150-158, 376, 428, 611-17).

needs a very large number of samples . . . running through it very quickly." (CCFF ¶ 1217).

Consequently, Dr. Felton testified that {

(CCFF ¶ 1220).

Respondents likewise have failed to show that Thermo Fisher's NGS platform is a substitute for Illumina's NGS platform because of its higher cost, lower accuracy, and lower throughput—and the unanimous testimony of MCED test developers and even Thermo Fisher itself confirm that its NGS platform is not an option.

### c. Respondents Ignore Extensive Evidence Showing ONT Is Not an Alternative for MCED Tests

Respondents likewise ignore unequivocal testimony from MCED test developers that long-

read sequencers from ONT are not an alternative to Illumina's NGS platform. Illumina's NGS platforms are short-read sequencers, { (CCFF ¶¶ 894-95, 940-41). By contrast, ONT is a long-read sequencer that { (CCFF ¶¶ 902-05). Because MCED tests entail sequencing billions of very short DNA fragments, *see, e.g.*, (CCFF ¶ 1119), MCED test developers testified that long-read sequencers are not a substitute for Illumina's short-read NGS platforms. CC Post-Tr. Br. at 17; (CCFF ¶¶ 893-914, 1370-98). Nevertheless, Respondents claim that ONT is a viable alternative to Illumina's short-read NGS platforms, even though they have put forward no evidence that ONT has any MCED test developer customers, or even any prospective MCED test developer customers. Resp. Post-Tr. Br. at 78-79. Respondents' baseless assertion is unsupported by testimony from even a single fact witness. Instead, Respondents rely on irrelevant documents

which they improperly attribute to ONT<sup>52</sup> and inappropriately use the testimony of their expert, Dr. Cote to support factual propositions, in blatant contravention of this Court's order. Resp. Post-Tr. Br. at 78-79 (citing RPFF ¶¶ 779, 779.1-3); *see also* (Response to RPFF ¶¶ 779, 779.1-3) (explaining why Respondents' proposed findings are unsupported). The actual fact witnesses—MCED test developers—instead testified that ONT's long read technology is not suitable for use in MCED tests.

MCED test developers testified that "highly inefficient" long-read sequencers like ONT's NGS platform are not alternatives for their MCED tests. (CCFF ¶ 1361, 1370-72, 1374-77, 1379-81, 1383-98). Like the MCED test developers, Illumina does not consider ONT's long-read platform to be a competitor in oncology applications, let alone MCED testing. Illumina's CEO Francis deSouza has repeatedly told investors that Illumina does not expect to compete with long-read platforms in oncology due to the far higher cost and lower accuracy of long-read. (CCFF ¶ 1346, 1357-59).

Respondents deceptively claim that ONT's long-read platform is less expensive than Illumina's platform. But as was explained *supra*, this claim relies on the misleading use of an irrelevant metric that Respondents are using to muddle the overwhelming weight of the evidence that shows ONT is not an alternative. As Illumina's CEO, Francis deSouza explained to investors, long-read is not less expensive than short-read, but on the contrary "short reads are just simply the better technology in terms of accuracy, in terms of price performance. The price gap can be 10x

<sup>&</sup>lt;sup>52</sup> See, e.g., RX3543, a document which Respondents purportedly captured from ONT's website, but improperly name 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. See (Response to RPFF ¶¶ 779, 779.2-3).

between what you can do in short reads and what you can do in long reads. The raw accuracy is []higher on short reads. . . . [In markets like] liquid biopsy [] [y]ou're looking at fragments that are under 200 base pairs long. And so, you're not willing to make a trade-off in accuracy or cost just to be able to read 10,000 base pairs." (CCFF ¶ 1359). Moreover, even if the cost were lower, it would be irrelevant, because long-read sequencers are not a substitute for short-read sequencers for MCED tests due to their lower accuracy and lower throughput. *See, e.g.*, (CCFF ¶ 1360, 1367, 1374, 1380, 1393).

2. Respondents Fail To Carry Their Burden To Show that Entry by New NGS Platform Developers Is Timely, Likely, or Sufficient To Prevent Harm From the Acquisition

Respondents bear the burden of showing that new entry of NGS platforms will be timely, likely, and sufficient to counteract the anticompetitive effects of the Acquisition, but have done nothing to satisfy this burden. *See AT&T*, 916 F.3d at 1032; *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990); *see also H&R Block*, 833 F. Supp. 2d at 73. Respondents point to a handful of firms, none of which offer an NGS platform that is remotely comparable to Illumina's current NGS platform, *see* (CCFF ¶¶ 1212-1398), and assert that they will be "likely to enter the market in the near future." Resp. Post-Tr. Br. at 80. Not a single MCED test developer views any of these platforms as an alternative to Illumina. On the contrary, the only testimony by MCED test developers regarding these platforms unequivocally shows that MCED test developers view the platforms as inferior to Illumina's NGS platform, { } and unlikely to enter the market. (CCFF ¶¶ 1286-95, 1302-19, 1325-45, 1613-20, 1646-48, 1677-83, 1717-23); *see also FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 352 (3d Cir. 2016) (finding

entry would not be timely, likely, or sufficient due to "extensive testimony" from customers that that the potential entrants were not substitutes).

Respondents also argue that Complaint Counsel bears the burden of disproving their claims of entry as part of its *prima facie* case. Resp. Post-Tr. Br. at 130-31. To the contrary, 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. CC Post-Tr. Br. § 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

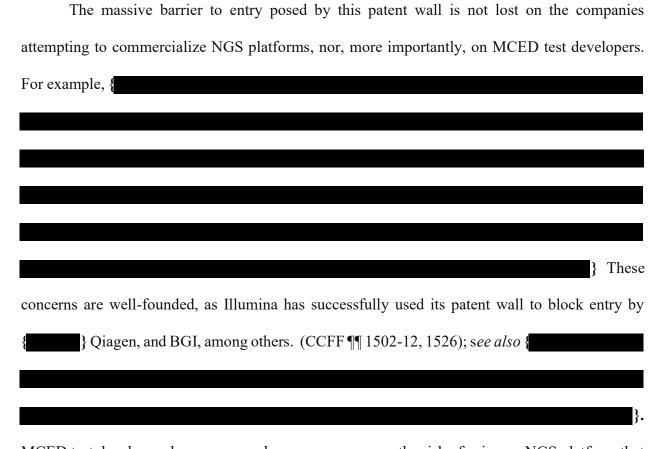
counteract anticompetitive effects that would otherwise be expected." H&R Block, 833 F. Supp. 2d at 73. Such entry or expansion must be "timely, likely, and sufficient in its magnitude, character, and scope' to counteract a merger's anticompetitive effects." Anthem, 236 F. Supp. 3d at 222-24 (quoting H&R Block, 833 F. Supp. 2d at 73). For entry to be timely, "entry must be rapid enough to make unprofitable overall the actions causing those effects and thus leading to entry, even though those actions would be profitable until entry takes effect" and "rapid enough that customers are not significantly harmed by the merger, despite any anticompetitive harm that occurs prior to the entry." Anthem, 236 F. Supp. 3d at 222 (citing Horizontal Merger Guidelines § 9.1). For entry to be likely, Courts look to "the history of entry" as "a central factor in assessing the likelihood of entry in the future." Id. (quoting FTC v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 56 (D.D.C. 1998)). Finally, entry is only sufficient if it has "the magnitude, character, and scope to counteract a merger's anticompetitive effects" and "fill the competitive void that will result" from the merger. Anthem, 236 F. Supp. 3d at 222 (citing CCC Holdings, 605 F. Supp. 2d at 59). Critically, entry must be "of a sufficient scale to compete on the same playing field as the merged firm." Id. (quoting Chi. Bridge & Iron Co. v. FTC, 534 F.3d 410, 430 (5th Cir. 2008)).

Not only is entry Respondents' burden under *Baker Hughes*, but Respondents have the burden to substantiate their factual claims of entry under the Part 3 rules. Respondents make factual representations that certain companies will launch NGS platforms, such platforms will be viable alternatives to Illumina for MCED testing, and the availability of said platforms will counteract Illumina's ability to harm Grail's rivals. *See, e.g.*, Resp. Post-Tr. Br. at 130. 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)). Respondents have failed to meet their burden of proof for their factual propositions of entry here. See also CC Post-Tr. Br. § II.F.1. Respondents elide the fundamental fact that commercialization of an NGS platform is a challenging process. The history of entry is a "central factor in assessing the likelihood of entry in the future." *Anthem*, 236 F. at 222 (quoting Cardinal Health, 12 F. Supp. 2d at 56). Large, established companies including Roche, { Quantum Bound of Control of dollars attempting unsuccessfully to commercialize NGS platforms that are comparable to Illumina's platform. (CCFF ¶ 1502-12, 1526). Still other companies, like Omniome, have spent years and millions of dollars trying to develop an NGS sequencer and have yet to complete development. (CCFF ¶ 1509-12). Due to these challenges, "there [has been] really no NGS compan[y] that could compete with Illumina in a meaningful, material way" for the past decade. (CCFF ¶ 1515). Respondents fail to explain why, after a decade of established firms and startups alike failing, new entry is suddenly likely, let alone how it would be sufficient to counter the anticompetitive effects of the Acquisition.

Instead, Respondents hint that the expiration of "certain Illumina patents . . . in 2022 and 2023" will lead to new entry. Resp. Post-Tr. Br. at 80. But Illumina has told its investors a very different story. Illumina's SVP and Chief Technology Officer, Dr. Alex Aravanis, prepared a response to anticipated investor questions for a large group investor meeting on Monday, February 22, 2021, representing that "Illumina owns a spectrum of IP covering various improvements that enable Illumina's superior sequencing accuracy, speed, and efficiency. These patents and pending

applications have expiration dates ranging from 2023 to beyond 2030 . . . [and] touch every aspect of the sequencing workflow." (CCFF ¶ 1517). And in January 2021, Illumina told its investors that it has "an extensive intellectual property portfolio" including "exclusive licenses to 901 issued U.S. patents and 650 pending U.S. patent applications" covering various aspects of its platform that expire as late as 2041. (CCFF ¶ 1518). Moreover, even if a new entrant does succeed in launching and commercializing a comparable NGS platform, it still would not be a sufficient alternative due to the lengthy time and massive costs associated with switching platforms. (CCFF ¶ 1768-1901). Respondents completely ignore these issues.



MCED test developers have expressed grave concern over the risk of using an NGS platform that

does not have clear freedom to operate—a risk that they do not bear if they use Illumina's NGS platform. (CCFF ¶ 1522, 1526, 1573-76).

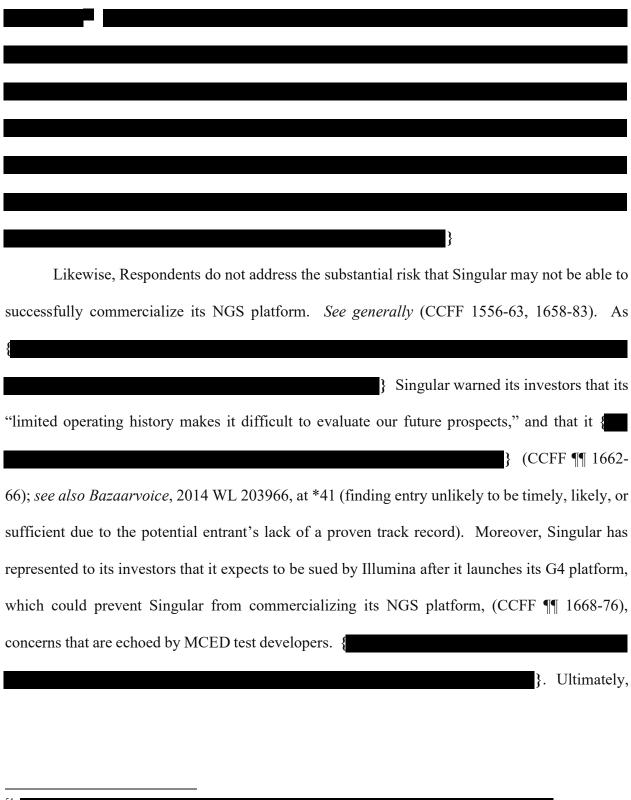
Analysis of each of Respondents' alleged potential entrants show that Respondents have not met their burden of showing that entry or expansion "can counteract anticompetitive effects that would otherwise be expected" from the Acquisition, *H&R Block*, 833 F. Supp. 2d at 73, and that such entry or expansion will be "timely, likely, and sufficient in its magnitude, character, and scope' to counteract [the Acquisition's] anticompetitive effects." *Anthem*, 236 F. Supp. 3d at 222-24.<sup>53</sup>

#### **Singular**

Respondents misrepresent that Singular's NGS platform is an alternative to Illumina's platforms in contrast to the record which shows Singular will not be a viable option for MCED test developers. Resp. Post-Tr. Br. at 80. In support of their claim, Respondents misleadingly assert that Singular's reported performance characteristics are comparable to those of Illumina's NextSeq and NovaSeq systems. This is contradicted {

| In fact, Singular's sequencer only has a target throughput of the sequencer o

<sup>&</sup>lt;sup>53</sup> Tellingly, Respondents only called a single witness from a potential NGS entrant at trial, and instead rely on improperly attributed documents, misquoted third-party testimony, improper expert testimony, and the unfounded, self-serving testimony of Illumina executives to argue that entry will be timely, likely, and sufficient.



by contrast the NovaSeq only requires two flow cells to achieve 20 billion reads per run. (CCFF ¶ 1049, 1617).

Singular may require "substantial additional funding," and may be unable to obtain it. <sup>33</sup> (CCFF
¶¶ 1666-67). {
} As such,
Respondents have failed to establish that Singular will be a timely, likely, or sufficient entrant into
the NGS market. See FTC v. Sysco Corp., 113 F. Supp. 3d 1, 81 (D.D.C. 2015) (finding that entry
would not be timely, likely, or sufficient due to the inability of new entrants to replicate the
capabilities of the merged firm).
<u>Ultima</u>
}. Ultima has not yet begun
marketing its NGS platform to the broader market because, as Ultima's Chief Commercial Officer,
Josh Lauer, testified, "[w]e're simply not ready." (PX7119 (Lauer (Ultima) Dep. at 26-27).

<sup>&</sup>lt;sup>55</sup> Singular would likely struggle to raise additional capital. Velarde did not dispute that Singular's stock price had declined by nearly 50 percent between its IPO in May 2021 and trial. (Velarde (Singular Genomics) Tr. 4571). It has continued to plummet post-trial.

} Illumina likewise has
shown no sign that it views Ultima as a meaningful competitor, as Illumina CEO Francis deSouza
testified at trial that { Clearly, Respondents
have failed to show that Ultima will be a timely, likely, or sufficient entrant into the NGS market.
See Bazaarvoice, 2014 WL 203966, at *43 (finding entry unlikely to be timely, likely, or sufficient
due to disinterest from potential customers); see also FTC v. CCC Holdings Inc., 605 F. Supp. 2d
26, 53-54 (D.D.C. 2009) (holding that entry would not be sufficient due to the technical inferiority
of the potential entrant).

#### Roche

Despite Respondents' claims, overwhelming evidence shows that entry by Roche will not be timely, likely, or sufficient to counter the anticompetitive effects of the Acquisition. Roche has spent nearly a decade and millions of dollars unsuccessfully attempting to develop an NGS platform, (CCFF ¶ 1501), {

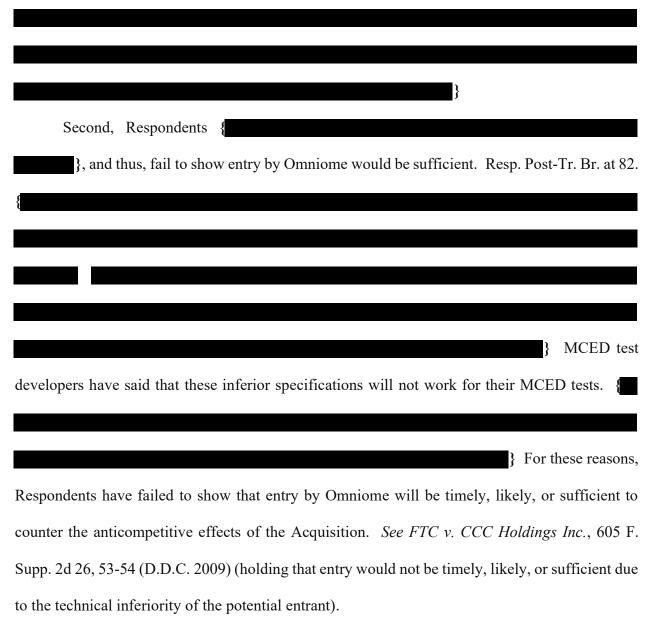
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<u>Omniome</u>
Finally, Respondents tout Omniome as a future alternative to Illumina's NGS platform for MCED test developers, despite having failed to demonstrate that Omniome's entry is timely,
likely, or sufficient. First, {



Assuming that one of these companies could enter in a timely, likely, and sufficient manner, Respondents appear to argue that MCED test developers could easily switch to a new platform. This stands in stark contrast to testimony from each and every MCED test developer that testified at trial and explained switching NGS platforms is extremely challenging, expensive, time consuming, and risky. CC Post-Tr. Br. § II.F.1.b; (CCFF ¶¶ 1768-1901).

In sum, Respondents fail to show that entry is timely, likely, and sufficient to counter the harm from the Acquisition. For each of their putative entrants, Respondents have not estimated a date that they will be commercially available for MCED tests to run, merely offering projections for general commercial launch dates. Resp. Post-Tr. Br. at 77-82. This factor is crucial—the harm from the Acquisition is happening now, as the evidence clearly shows that each MCED developer is designing their test for a specific Illumina sequencer, and they are starting or in the midst of clinical trials. CC Post-Tr. Br. at 20-23; (CCFF ¶ 2061-2104, 2320, 2324, 2393-98, 3589). Given the increased switching costs that occur as a developer gets further along in the development process, entry cannot wait for years. CC Post-Tr. Br. at 14, 129-30, 152-54; (CCFF ¶ 1872-1901). Moreover, Respondents have also failed to establish that entry will be sufficient. Each of these entrants fails in key performance specifications that are essential for MCED test developers to compete effectively. Accordingly, Respondents have failed to meet their burden of showing that new entry will be timely, likely, or sufficient to counteract the substantial anticompetitive effects of the Acquisition.

### III. Complaint Counsel Met Its Burden To Show Reasonable Probability of Competitive Harm

Complaint Counsel presented extensive ordinary course documents and testimony, bolstered by expert opinion, to meet its burden to show that Illumina's acquisition of Grail poses a reasonable probability of harming competition in the research, development, and commercialization of MCED tests in the United States. Through these reliable, diverse sources of evidence, Complaint Counsel showed that Illumina will have the post-Acquisition ability and incentive to harm Grail's rivals now and for the foreseeable future, hampering their ability to

provide a competitive constraint to Grail, ultimately inuring to the detriment of American consumers. See CC Post-Tr. Br. § II.E.

In their attempt to rebut Complaint Counsel's strong showing of anticompetitive effect, Respondents oscillate between two extremes. At one end, they ask this Court to impose novel legal standards on Complaint Counsel that require hyper-technical economic analyses—which they do not present themselves—without any basis in law or logic. *See, e.g.*, Resp. Post-Tr. Br. at 90-92. At the other end, they criticize Complaint Counsel's analyses as being too theoretical and inconsistent with so-called "economic realities"—despite Complaint Counsel's reliance on ordinary course documents and reliable, corroborated testimony from a diverse array of independent market participants that consistently reflect the economic reality of ongoing innovation competition in the MCED market. Resp. Post-Tr. Br. at 87, 94. Respondents support their alleged "economic realities" by presenting this Court with fact-free theories that rely solely on their economic experts' thought experiments. *See, e.g.*, Resp. Post-Tr. Br. at 126-29. As the foregoing explains, Respondents failed to undermine Complaint Counsel's *prima facie* case, and thus failed to meet their burden under governing precedent.

### A. Complaint Counsel's *Prima Facie* Case Reflects Market Realities Bolstered by Economics and Real-World Evidence

Respondents fail to respond to Complaint Counsel's strong *prima facie* showing of potential competitive harm head-on. Instead, they push this Court to adopt unorthodox, hypertechnical standards for vertical merger enforcement that bear no resemblance to either the language in the Clayton Act or any case law interpreting the same. Resp. Post-Tr. Br. at 87-92, 95, 130-31. Respondents argue that Complaint Counsel must not only show a substantial likelihood of antitrust effects but also disprove all aspects of a Clayton Act challenge for which defendants traditionally

bear the burden—such as entry, efficiencies, and remedy—as part of Complaint Counsel's *prima facie* case, conveniently leaving no burden for themselves. Resp. Post-Tr. Br. 88-89, 95, 130-31. While shirking their own burdens, Respondents ask this Court to elevate the Government's *prima facie* burden to new heights, exceeding the already-heightened burden in inapplicable Sherman Act monopolization cases in direct contradiction case law that mandates a lower standard for Clayton Act cases, not a higher one. *See, e.g., Microsoft*, 253 F.3d at 69; *Brown Shoe*, 370 U.S. at 328-29 (noting "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").

In addition to requiring Complaint Counsel to bear the burden of proving every aspect of the Clayton Act analysis, Respondents argue that 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," while accounting for the "timing and magnitude of potential harm versus likely benefit" from the Acquisition. Resp. Post-Tr. Br. at 90-91. While that is not the law, Complaint Counsel presented a detailed economic analysis to corroborate the ordinary course documents and testimony that, alone, would be sufficient to meet its burden under the Clayton Act.

#### 1. Respondents' Characterization of Complaint Counsel's Burden is Incorrect

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. *Baker Hughes*, 908 F.2d at 982-83. 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. *Id.* at 983.

But Respondents argue that the *Baker Hughes* framework is fundamentally different for vertical cases than horizontal cases, citing no caselaw supporting such a claim.<sup>58</sup> Resp. Post-Tr. Br. at 87. In so doing, Respondents seek to turn *Baker Hughes* on its head by compressing the entire burden of production—including disproving Respondents' unsubstantiated rebuttal arguments—into Complaint Counsel's *prima facie* burden.<sup>59</sup> Respondents misstate the law to

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<sup>&</sup>lt;sup>58</sup> Instead, Respondents support this argument solely through a curated list of general statements suggesting vertical mergers may, in some situations, generate more efficiencies or otherwise be more procompetitive than horizontal mergers. Resp. Post-Tr. Br. at 86-88. Respondents' cherry-picked statements are not representative of an economic consensus and do 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-Tr. Br. at 91 n.13 (citing Crawford et al.).

<sup>&</sup>lt;sup>59</sup> 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).

avoid spotlighting the dearth of facts that a faithful application of *Baker Hughes* reveals. Respondents mischaracterize the *Baker Hughes* framework for the following reasons.

First, Respondents incorrectly argue that the application of *Baker Hughes* differs between horizontal and vertical cases because there is no relevant market concentration presumption in vertical cases. Resp. Post-Tr. Br. at 86-89. 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 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.

Second, Respondents conflate the Government's ultimate burden of persuasion with its burden of production at the *prima facie* stage. The Government's burden of persuasion does not require it to produce evidence to negate Respondents' potential affirmative defenses and rebuttal points at the initial *prima facie* case stage—without first requiring Respondents to produce evidence supporting their rebuttals and affirmative defenses. Such a standard would burden Complaint Counsel at the outset with proving negatives of any unsubstantiated assertions Respondents put forth. Rather, Complaint Counsel's burden of persuasion simply means that it

<sup>&</sup>lt;sup>60</sup> 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).

bears the "ultimate burden of persuading the trier of fact," *Baker Hughes*, 908 F.2d at 991 (citations and quotations omitted), in other words persuading the Court that a preponderance of the evidence shows the Acquisition is likely to substantially lessen competition. *See AT&T*, 310 F. Supp. 3d at 189 (D.D.C.) ("The Government 'has the ultimate burden of proving a Section 7 violation by a preponderance of the evidence.") (quoting *H&R Block*, 833 F. Supp. 2d at 49); *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1218 (11th Cir. 1991) ("[T]o satisfy section 7, the government must show a reasonable probability that the proposed transaction would substantially lessen competition in the future.").

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-Tr. 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. 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

<sup>&</sup>lt;sup>61</sup> 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.

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.<sup>62</sup>

Respondents cite no precedent that supports their novel burden-shifting framework, underscoring its divergence from antitrust principles. Respondents attempt to invoke AT&T, Resp. Post-Tr. Br. at 88, but that case contradicts their claims. The AT&T district court endorsed the applicability of *Baker Hughes* for vertical mergers and explicitly rejected the argument that the Government must account for defendants' efficiencies as part of its *prima facie* case. 310 F. Supp. 3d at 191 n.17. The only procompetitive benefits the district court incorporated into its assessment were those conceded by the Government, for which the burden of production was not at issue.

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<sup>&</sup>lt;sup>62</sup> To the extent Respondents contend Complaint Counsel's *prima facie* showing of harm is "inaccurate, upwardly biased (*i.e.*, government friendly) prediction[] of . . . competitive harm," Resp. Post-Tr. Br. at 89, *Baker Hughes* affords them the opportunity to attack Complaint Counsel's case on rebuttal and attempt to undercut its ability to meet its ultimate burden of persuasion. *Baker Hughes*, 908 F.2d at 983, 990-91; *AT&T*, 310 F. Supp. 3d at 191 n.17 (D.D.C.).

<sup>&</sup>lt;sup>63</sup> Respondents mischaracterize 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.

<sup>&</sup>lt;sup>64</sup> Further damaging to Respondents' argument, the district court applied *Baker Hughes* in a manner consistent with horizontal cases and thus Complaint Counsel's interpretation of the law. In *AT&T*, the Government presented a *prima facie* case that defendants sufficiently "undermined and discredit[ed]" with their own proffered evidence, ultimately leading the court to conclude the Government "failed to carry its ultimate burden of persuasion" with respect to effects. 310 F. Supp. 3d at 191 n.17 (D.D.C.) (quoting *Baker Hughes*, 908 F.2d at 983, 990-91). That is a direct application of the *Baker Hughes* framework, going so far as to quote *Baker Hughes*' discussion of defendants' rebuttal burden

Given the impracticality and unprecedented nature of such an approach, it is no wonder the district court in *AT&T* explicitly rejected such a position "as a matter of law and logic." 310 F. Supp. 3d at 191 n.17.

As part of Respondents' efforts to marshal support for their arguments throughout their brief, they cite an ostensibly independent article that, in fact, Respondents themselves helped manufacture: Bruce Kobayashi and Timothy Muris' article about the merits of this case. Resp. Post-Tr. Br. at 91 (citing 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"]). 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.

when discussing AT&T's successful rebuttal of the Government's case. The district court concluded that, after defendants' successful rebuttal, the Government could not meet its "ultimate burden of persuasion," which is exactly what *Baker Hughes* outlined after successful rebuttals in horizontal cases. In addition, the district court did not address defendants' evidence of procompetitive justifications because the Government had not presented enough evidence of anticompetitive effect after AT&T undermined its evidence. 310 F. Supp. 3d at 191 n.17 (D.D.C.).

The D.C. Circuit interpreted the lower court opinion the same way. It noted that "the government must make a 'fact-specific' showing that the proposed merger is 'likely to be anticompetitive.' . . . "Once the *prima facie* case is established, the burden shifts to the defendant to present evidence that the *prima facie* case 'inaccurately predicts the relevant transaction's probable effect on future competition,' or to 'sufficiently discredit' the evidence underlying the *prima facie* case. Upon such rebuttal, 'the burden of producing additional evidence of anticompetitive effects shifts to the government, and mergers with the ultimate burden of persuasion, which remains with the government at all times." (citations omitted) (quoting *United States v. Anthem, Inc.*, 855 F.3d 345, 349 (D.C. Cir. 2017); *Baker Hughes*, 908 F.2d at 983, 991). And, according to the D.C. Circuit, defendants rebutted the Government's *prima facie* case. Specifically, "[AT&T] purported to show through its own experts [among other evidence] that the government's *prima facie* case inaccurately predicted the proposed merger's probable effect on competition." 916 F.3d at 1036. When the burden of proof shifted back to the Government and merged with the burden of persuasion, the Government had not met its burden of persuasion as to the "first-level" issue of whether there was sufficient anticompetitive effect. 916 F.3d at 1038; 310 F. Supp. 3d at 191 n.17; *see also Baker Hughes*, 908 F.2d at 983. Thus, both the *AT&T* district court's analysis, and the subsequent summary by the D.C. Circuit, contradict Respondents' interpretation of *Baker Hughes*' application to vertical mergers.

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. {
} 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. <sup>65</sup> Kobayashi & Muris at 36.

<sup>&</sup>lt;sup>65</sup> 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 re 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. Juris.* § 3975 (5th ed. 2022)).

Essentially this article is 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, opinion testimony to get around this Court's prior rulings and to sidestep the procedures designed to ensure a fair trial.

A proper application of the *Baker Hughes* framework shows that Complaint Counsel met its *prima facie* burden to show the Acquisition poses a reasonable probability of competitive harm.<sup>67</sup> Respondents have fallen far short of presenting evidence that rebuts Complaint Counsel's case, and thus Complaint Counsel has met its ultimate burden of persuasion here.

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<sup>66</sup> While the advocacy presented in this article deserves no weight, it is also incorrect in its substantive points. For example, it argues that the Vertical Merger Guidelines advocated a legal requirement that the Government must balance EDM with anticompetitive harm as part of its *prima facie* case. Kobayashi & Muris at 12; Resp. Post-Tr. Br. at 90. That is misleading. The Vertical Merger Guidelines did not discuss accounting for EDM as requirement of a *prima facie* case, they merely noted that Agencies may evaluate anticompetitive effects and substantiated, merger-specific EDM as part of the ultimate assessment of whether a transaction may harm competition. In fact, the Guidelines noted at the outset that they "neither dictate nor exhaust the range of evidence the Agencies may introduce in litigation." *Vertical Merger Guidelines* at 2 n.3. Moreover, the authors' argument that EDM should be treated differently than other efficiencies is directly contradicted by Respondents' other cited economic articles. Baker et al. at 30-35 (arguing EDM should be treated as other efficiencies for antitrust analysis and expressing concern about "suggest[ing] to the parties and a court that the agency must demonstrate the extent (or lack) of EDM, rather than placing the burden of producing evidence of cognizable EDM on the merging firms, where it belongs"); *see also* Crawford et al. at 3 (noting that "surprisingly little empirical work has documented [EDM] effects" and likening the assumption that "vertical integration should be expected to eliminate double marginalization" to how doctors thought opioids were rarely addictive based on "weak, weak, weak data").

<sup>&</sup>lt;sup>67</sup> Respondents invoke AT&T to say that "much more is required" than relying on third-party testimony that is "speculative, based on unproven assumptions, or unsupported." Resp. Post-Tr. Br. at 86. But 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). 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. 310 F. Supp. 3d at 219 (D.D.C.). Such deficiencies 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).

# 2. The Law Does Not Require an Economic Model To Prove a Reasonable Probability of Competitive Harm

a. The Law Does Not Require an Economic Model To Account for "All The Various Economic Factors that Arise in an Industry"

Respondents argue that Complaint Counsel's *prima facie* case fails because it has not adduced "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," simultaneously accounting 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.<sup>68</sup>

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

<sup>&</sup>lt;sup>68</sup> Respondents invoke AT&T to say that "much more is required" than relying on third-party testimony that is "speculative, based on unproven assumptions, or unsupported." Resp. Post-Tr. Br. at 86. But 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). 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. 310 F. Supp. 3d at 219 (D.D.C.). Such deficiencies 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).

Likewise, Respondents' citations to *Fruehauf* and *Hammermill* are unavailing. Those cases contain no reference to an economic model or lack thereof, and in fact both reaffirm the *Brown Shoe* analysis that potential foreclosure approaching "monopoly proportions" is determinative in itself without such models. *Fruehauf*, 603 F.2d at 354 (noting a "per se" rule was adopted "where the share of the market foreclosed reaches monopoly proportions") (citing *Brown Shoe*, 370 U.S. at 328); *United States v. Hammermill*, 429 F. Supp. 1271, 1293 (W.D. Pa. 1977) ("Because we were involved in a vertical integration where the share of the market foreclosed does not approach monopoly proportions it became necessary to undertake an examination of various economic and historical factors to determine whether the arrangement under review is of the type Congress sought to proscribe.") (citing *Brown Shoe*, 370 U.S. at 328). Not only does neither case support Respondents' claim, both cases directly contradict it.

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.

Left without precedent, Respondents rely predominantly on their economic expert, Dr. Carlton, to make economic arguments to support their novel legal burden. <sup>69</sup> Resp. Post-Tr. Br. at 90. Clearly Dr. Carlton is not qualified to opine on legal requirements and should be disregarded on that basis. Despite their mischaracterization of precedent, Respondents ignore a simple fact that dismantles their argument: the Government has successfully litigated many vertical merger cases over several decades—from the district court level to the Supreme Court—yet no court required the type of economic model Respondents seek to mandate here. *See, e.g., Brown Shoe,* 370 U.S. 294; *Ford Motor,* 405 U.S. 562; *U.S. Steel Corp. v. FTC,* 426 F.2d 592 (6th Cir. 1970); *In re Union Carbide Corp.,* 59 F.T.C. 614, 1961 WL 65409 (1961).

#### b. Although Not Required, Dr. Scott Morton Presented Both a Qualitative Economic Analysis and an Economic Model

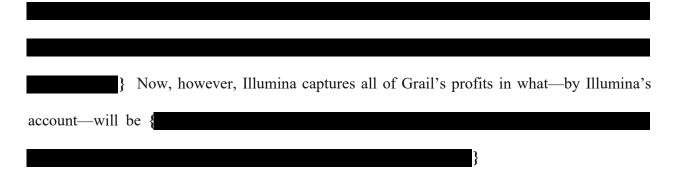
Respondents claim that Complaint Counsel did not present an economic model to support its case. Resp. Post-Tr. Br. at 90-92. But Complaint Counsel presented an economic model and

<sup>&</sup>lt;sup>69</sup> Respondents also rely on an article by Gregory Crawford et al. to suggest that an empirical analysis is required for determining if a vertical merger may harm competition here. Resp. Post-Tr. Br. at 91 n.13. But their quote 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). Respondents' 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 their argument, it undercuts their 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." *Id.* at 3 (noting that "surprisingly little empirical work has documented [beneficial EDM] effects").

qualitative economic analysis, although that is merely one piece of a wide array of evidence in the
record supporting Complaint Counsel's case establishing a reasonable probability of competitive
harm. Dr. Scott Morton, Complaint Counsel's economic expert, outlined the effects of the
Acquisition in detail, including using {
} Her expert opinion is bolstered by ordinary course documents
demonstrating that {
} And more generally,
as the overwhelming evidence makes clear, Illumina will have the ability and incentive to harm
competition. (CCFF $\P\P$ 2607-4164).
Next, Respondents argue that Dr. Scott Morton failed to consider Respondents'
unsubstantiated efficiencies claims. Resp. Post-Tr. Br. at 91-92 (mischaracterizing Dr. Scott
Morton's reasoning as "assum[ing] no efficiencies" and not {
falsely claiming evidence of "huge efficiencies" is "undisputed"). However, {
} While

a Clayton Act claim, *see*, *supra*, § III.A.2.a, such evidence is present here and merely adds to the already overwhelming evidence of potential harm in the MCED test market.

Aside from Respondents' arguments regarding the alleged need for a quantitative analysis, they also argue that Complaint Counsel did not prove Illumina's incentives vis-à-vis Grail's rivals will be different post-Acquisition, claiming Illumina's incentives to favor Grail existed pre-Acquisition as well. Resp. Post-Tr. Br. at 92-93. Contrary to Respondents' representations, Complaint Counsel proved that the Acquisition changed Illumina's incentives in its relationships with Grail's rivals. CC Post-Tr. Br. § II.E.1.b; (CCFF ¶¶ 3079-3569). While pre-Acquisition Illumina retained a small stake in Grail and received a , that arrangement did not give Illumina the same level of incentive to favor Grail as it does post-Acquisition. See { As contemporaneous documents during Illumina's original spin-off of Grail note, Illumina had an arms-length relationship with Grail. (CCFF ¶ 3732-42). After the spin-off, Grail was "required [to be] truly independent" so that Illumina could "avoid accounting for [its] losses as an equity method investment." (CCFF ¶ 3734). And according to Illumina, the Grail spin-off "actually leveled the playing field" for Grail's competitors. (CCFF ¶ 3735); see also {



## c. It Is Inappropriate To Consider Any Effect of Remedies Before a Determination of Competitive Harm

Respondents incorrectly assert that, rather than treating their Open Offer as a conduct remedy consistent with Section 7 precedent, Complaint Counsel must disprove the Open Offer's purported "effects" as part of its *prima facie* case. Resp. Post-Tr. Br. at 94-95 ("Complaint Counsel was required to account for the effects of the Open Offer, just as it as [sic] required, as part of its prima facie case, to account for all relevant, real-world economic facts . . . ."). There is no logical or precedential basis for this argument. The Open Offer is a proposed remedy as indicated on its face. The preamble of Respondents' Open Offer states:

In connection with Illumina Inc.'s proposed acquisition of GRAIL, Inc. (the 'Transaction'), Illumina is irrevocably offering to [COMPANY] the terms enclosed ... to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors .... To address these concerns, these terms will be offered ....

(PX0064 at 001 (Illumina Open Offer agreement, Mar. 30, 2021)); *see also* Respondents' Mot. for Conference to Facilitate Settlement 6-7 (F.T.C. July 13, 2021) (characterizing the Open Offer as "a consent agreement with protections in place to address the FTC's purported concerns").

<sup>&</sup>lt;sup>70</sup> Legally requiring Complaint Counsel to "account for all relevant, real-world economic facts" at the *prima facie* stage flatly contradicts the *Baker Hughes* burden-shifting framework—which Respondents agree applies here—that traditionally burdens Respondents with showing "economic facts" such as entry, efficiencies, and/or a remedy undermine or discredit Complaint Counsel's *prima facie* case. *See, supra*, § III.A.1.

Moreover, the Open Offer is conditional on the closing of the Acquisition. (PX0064 at 001 (Illumina Open Offer agreement, Mar. 30, 2021)). Respondents' behavioral remedy is in direct contrast to their cited cases where merging parties entered into permanent divestiture agreements (*i.e.*, structural remedies) that changed market structure. For example, 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.<sup>71</sup>

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* CC Post-Tr. Br. § 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.

Respondents' reliance on the D.C. Circuit opinion in AT&T to contradict this precedent is misplaced. As an initial matter, the AT&T 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

<sup>&</sup>lt;sup>71</sup> For completeness, Respondents' citation to *Arch Coal*, Resp. Post-Tr. Br. at 95, erroneously cites to the court opinion when the quote itself is only from the court's denial of the Government's motion *in limine* to exclude any evidence of the divestiture agreement altogether. Mem. Op., *FTC v. Arch Coal, Inc.*, No. 04-0534, at \*3, \*7 (D.D.C. July 7, 2004) (noting that the "concurrent divestiture" "will in fact occur" so the court was "unwilling simply to ignore the fact of the divestiture"). Respondents attempt to analogize the *Arch Coal* concurrent divestiture agreement with their proposed behavioral remedy by characterizing it as a "post-acquisition commitment," but the commitment to divest problematic assets is completely different than the behavioral remedy proposal Respondents put forth here.

agreements as "amount[ing] to extra icing on a cake already frosted") (citations and quotations omitted). 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.).<sup>72</sup> The strained reading of a district court's dicta is no substitute for a framework outlined in decades of clear Clayton Act precedent.

Moreover, Respondents' argument is not persuasive. As explained extensively in Complaint Counsel's initial briefing, the Open Offer does not change Respondents' ability or incentive to disadvantage Grail's rivals. CC Post-Tr. Br. § II.F.3.b. There is no credible evidence that the Open Offer—{

}—will have any real-world effect on the new anticompetitive dynamic between Illumina and Grail's rivals.

### B. The Overwhelming Evidence Shows that MCED Test Developers Compete With Grail

Complaint Counsel produced robust evidence that MCED test developers compete with Grail in the research, development, and commercialization of MCED tests. *See* CC Post-Tr. Br. § II.B; (CCFF ¶¶ 1902-2594, 3189-3569). Respondents make two arguments in response: (1) Complaint Counsel failed to make a requisite showing of any "diversion" to Grail to establish the competitive significance of other MCED test developers and therefore Illumina's incentive to harm them; and (2) Complaint Counsel ignores the uncertainty around finalized MCED testing characteristics and their potential differentiation. As the foregoing explains, Complaint Counsel presented ample evidence that MCED test developers provide competitive constraints to Grail and

<sup>&</sup>lt;sup>72</sup> 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. *Id.* 

are likely to cannibalize its sales upon commercialization. Moreover, the evidence shows that while MCED test developers are innovating to improve their tests' characteristics, the tests are likely to be similar to Galleri and compete closely with it. *See* CC Post-Tr. Br. § II.B; (CCFF ¶¶ 1902-2594, 3189-3569).

#### 1. Although Not Required, Complaint Counsel Performed a Diversion Analysis

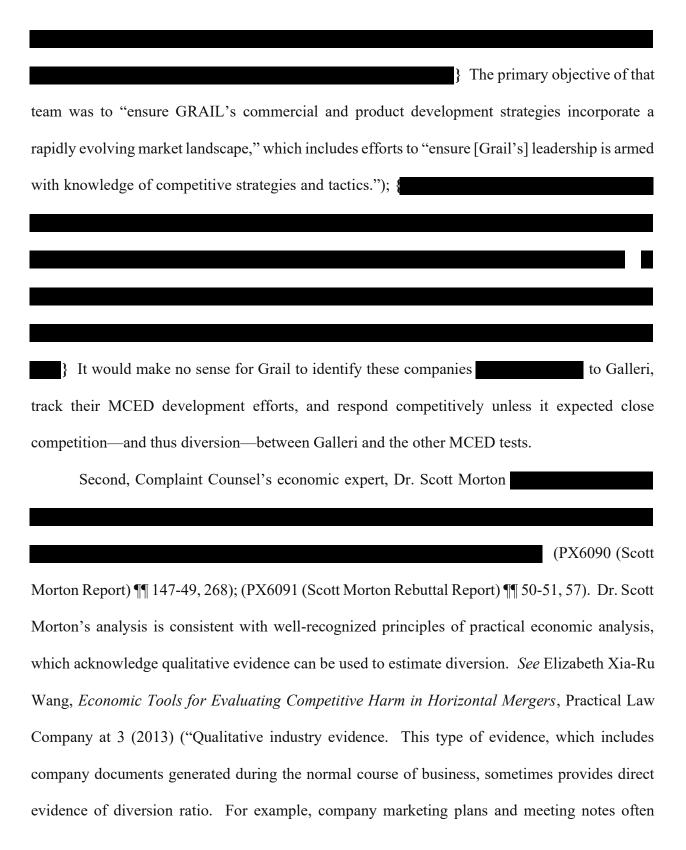
Respondents argue that the Complaint Counsel did not prove any "diversion," which Respondents define as showing "divert[ed] sales to GRAIL from GRAIL's purported rivals," Resp. Post-Tr. Br. at 97, and therefore Complaint Counsel did not meet its burden. In other words, if Illumina disadvantages or forecloses Grail's rivals, "diversion" calculates the extent to which the foreclosed rival's sales will be captured by Grail versus other competitors. See (CCFF ¶ 3099). 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. For example, 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)<sup>74</sup>—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.

In any event, the record is replete with evidence—including Respondents' own ordinary course documents—supporting the fact that MCED tests in development are likely to be close commercial substitutes for Galleri, (CCFF ¶¶ 3189-3569), thereby indicating significant diversion is likely in the future. *See, e.g.*, (CCFF ¶¶ 3404-05) (Grail's competitive intelligence team

<sup>&</sup>lt;sup>73</sup> In *HTI*, the district court found that there was insufficient incentive to harm competition by steering patients—or what Respondents misleadingly call "diversion"—towards an affiliate hospital: a finding based on myriad unique circumstances unrelated to economic diversion but nevertheless absent here. Most saliently, the physicians who allegedly had the incentive to steer patients away from the plaintiff hospital were also leasing office space from the plaintiff. The record was clear that the physicians had a "pressing need for office space" and were concerned that the plaintiff hospital "might exercise its eviction powers under the lease." *HTI*, 960 F. Supp. at 1137. This lessor-lessee relationship "creates a countervailing economic incentive for the physicians to maintain a cooperative association" with the plaintiff. *Id.* Clearly MCED test developers have no such post-Acquisition leverage against Illumina here. But the distinctions do not end there. In *HTI*, other factors constrained the physicians in referring patients to their affiliate hospital. The physicians deferred to their patient's choice of hospital when making a referral, inhibiting their ability to steer patients to their affiliate hospital. *Id.* Moreover, the proximity of the plaintiff hospital to the physicians' practice allowed them to be responsive to patients' needs in intensive care, creating an additional reason not to steer patient referrals to the affiliate hospital farther away. *Id.* Illumina faces no such constraints here.

<sup>&</sup>lt;sup>74</sup> *Crouse-Hinds* involved several facts not present here. The vertical merger involved low single-digit potential foreclosure and the company operated its acquired entities as "independent profit centers," both of which the court found persuasive. 518 F. Supp. at 433-34.



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, supra,* § 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).

### 2. Complaint Counsel Accounted for Continuously Developing Products and Differentiation

Respondents argue that Complaint Counsel did not address that MCED tests are still in development and might ultimately have differentiated characteristics. Resp. Post-Tr. Br. at 97-98, 100. To the contrary, Complaint Counsel addresses differentiation, as described *supra*, § I.B.2.b.ii. While MCED test developers—including Grail—continue to improve their tests along different qualitative metrics, this innovation competition is precisely among the harms the Acquisition threatens. *See* CC Post-Tr. Br. § II.B.3; (CCFF ¶¶ 3570-3668).

With respect to the fact that research and development of MCED tests is ongoing, Respondents ask this Court to adopt a myopic view of competition: unless products reach a point at which they are unchanged, by definition there will be too much "uncertainty" to assess their

competitive significance. *See, e.g.*, Resp. Post-Tr. Br. at 97-98. The implication of such a view is that antitrust does not reach markets where dynamic innovation is an axis of competition. Markets in which companies routinely improve products to enhance their competitive position—and change products in response to competitive pressures—would be immune from antitrust scrutiny under Respondents' interpretation of the law. But that is not the law. *See United States v. Anthem, Inc.*, 855 F.3d 345, 361 (D.C. Cir. 2017) (A "threat to innovation is anticompetitive in its own right."); *Union Carbide*, 1961 WL 65409, at \*35 (noting it is particularly important to prevent monopolies in "infant industr[ies] which appear[] destined for far greater expansion and growth. Strong and vigorous competition is the catalyst of rapid economic progress."). *See, supra*, § I.B.1.a (explaining that Respondents' purported standard would effectively eliminate antitrust enforcement in a dynamic market).

With respect to differentiation, Respondents seem to suggest that differentiated products do not compete or cannot be economic substitutes. That is not the law. Caselaw is clear that mergers involving differentiated products are subject to antitrust scrutiny. See, e.g., Otto Bock, 2019 WL 2118886, at \*20-21 (Chappell, A.L.J.) ("A merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising the price of one or both products above pre-merger level.") (quoting the Horizontal Merger Guidelines § 6.1). Respondents use a strawman argument to suggest that Complaint Counsel assumed "current differentiation does not matter" because the tests can "easily and swiftly jump

<sup>&</sup>lt;sup>75</sup> Respondents' own economic experts concede that innovation competition, including innovating to differentiate along product features and functions, is important. *See* (CCFF ¶ 3530) (Respondents' expert Dr. Katz testifying that R&D competition involved differentiating a firm's product to compete on different features or functions); (CCFF ¶ 3570) (Respondents' expert Dr. Carlton testifying that innovation harm is "a concern you should worry about" when examining the effects of a merger, and Dr. Katz testifying that "stifled" innovation "would be in my view a very bad thing").

from single- or -few-cancer tests to 50-cancer tests." Resp. Post-Tr. Br. at 108. From the outset, Respondents overstate the differences between Galleri and its rival tests. CC Post-Tr. Br. § II.B.1; CC Post-Tr. Reply Br. § I.B.2.b.ii.a; (CCFF ¶¶ 3189-3507). Such an unnuanced attack also ignores that differentiated products can be competitive with each other across different metrics, as the current innovation competition in the MCED test market already shows. *See, supra*, § I.B.2.b.ii.

#### C. Neither Lost NGS Sales Nor Reputational Consequences Will Constrain Illumina

Next, Respondents make two unsupported arguments: (1) Illumina's lost NGS sales will constrain Illumina from harming Grail's rivals; and (2) Illumina harming Grail's rivals will affect Illumina's reputation, thereby providing an additional constraint on Illumina outside of the MCED testing. Neither argument has merit. Illumina's potential lost NGS sales, even from complete foreclosure of all of Grail's rivals, is miniscule compared to its expected profits from Grail. Moreover, Illumina is not constrained by its reputation because its reputation is already poor and, in any event, Illumina's own Open Offer protects it from reputational damage that could, theoretically, come from harming Grail's rivals.

#### 1. Lost NGS Sales Will Not Constrain Illumina

Respondents argue that Illumina will not disadvantage Grail's rivals because Illumina will lose NGS sales in the process. Resp. Post-Tr. Br. at 111-12. Respondents attempt to justify their argument by stating, contrary to fact, that MCED test developers would "divert to rival sequencing platforms" such as Thermo Fisher or BGI. Resp. Post-Tr. Br. at 112. As discussed, *supra*, § II.B, there is overwhelming evidence that MCED test developers have no alternatives to Illumina for NGS platforms. *See also* CC Post-Tr. Br. §§ II.D.2, II.F.1.

Respondents also argue that, regardless of NGS platform competition, Illumina would suffer "enormous" losses even if Grail's rivals chose to "no longer invest in NGS applications on Illumina systems." Resp. Post-Tr. Br. at 112. That argument contradicts the weight of the record, including Illumina's own representations to its investors. First, there are massive benefits to Illumina if it protects Grail as the market leader. { Second, the potential losses to Illumina—even from complete foreclosure—are insignificant. Illumina's CEO 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."<sup>76</sup> (CCFF ¶ 3140). Respondents state that Illumina's "core business" remains and will remain NGS platforms, relying only on post-Acquisition self-serving testimony from Illumina's executives. Resp. Post-Tr. Br. 111-13. Notwithstanding the fact MCED testing is a small percentage of Illumina's "core business" today, (CCFF ¶ 3140), as Illumina's pre-Acquisition ordinary course documents show, Illumina seeks to { } In fact, Illumina justified the Acquisition to its Board of Directors in this way, {

<sup>&</sup>lt;sup>76</sup> Illumina can identify Grail's competitors, foreclose or otherwise disadvantage them separately from other customers, and thus minimize the revenue impacted to the small fraction from competing MCED test developers. *See* CC Post-Tr. Br. § II.E.1.a.i; (CCFF ¶¶ 2608-2701).

Thus, the immense multibillion-dollar benefit to protecting Grail's market position, the miniscule impact even complete foreclosure of Grail's rivals would have on Illumina's upstream sales, and Illumina's clearly articulated interest in make wholly unpersuasive Respondents' arguments that any foreclosure efforts would risk Illumina NGS sales. As Illumina's CEO, Francis deSouza, explained he has a fiduciary duty to his shareholders to maximize the combined firm's revenue. (CCFF ¶ 6086). To ensure the profitability Illumina promised its shareholders, Illumina needs to position Grail for success now.

#### 2. Reputation Risks Will Not Constrain Illumina

Respondents argue that "Complaint Counsel's theory of harm overlooks that an attempted foreclosure strategy would cause substantial harm to Illumina's reputation." Resp. Post-Tr. Br. at

<sup>&</sup>lt;sup>77</sup> Respondents attempt to cite to caselaw to support their argument, but these 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.]"). This is a significantly different situation than here, where Illumina supplies a critical input for which there are no alternatives today or for the foreseeable future. CC Post-Tr. Br. § II.D.2; supra § II.B. 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.

<sup>&</sup>lt;sup>78</sup> Respondents also argue that Illumina expects Grail to operate at a solution, so Illumina has no incentive to disadvantage Grail's rivals until Grail makes a profit. Resp. Post-Tr. Br. at 118. Regardless of whether Grail operates at a loss today, clearly Illumina expects Grail to earn massive future profits and has a fiduciary duty to ensure it maximizes its Grail's value. (CCFF ¶ 6086). Any argument that assumes that Illumina would not take actions now to ensure it maximizes Grail's—and therefore its own—profits later is illogical and contradicted by the weight of the evidence. (CCFF ¶¶ 3079-3569).

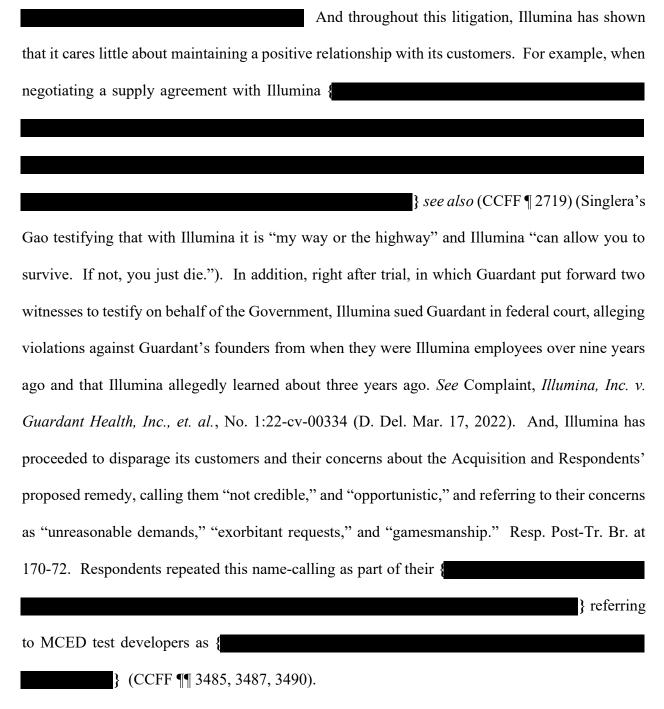
115. Respondents' support for Illumina's reputation comes only from self-serving testimony of Illumina executives or Respondents' paid experts—none of which control Illumina's actual reputation in the marketplace.<sup>79</sup> The record makes clear, however, that (1) Illumina already has a poor reputation among its customers; (2) even if Illumina's reputation could worsen, it would have no impact on Illumina's upstream sales; and (3) Illumina insulated itself against any potential reputational damage through its Open Offer.

First, despite Respondents' claims that Illumina's reputation is that of a "trusted supplier,"

Illumina's customers actually view Illumina as difficult and distrustful. See {

<sup>&</sup>lt;sup>79</sup> The only exception to this self-serving testimony includes Respondents' inaccurate claim that Dr. Scott Morton acknowledged {

<sup>(</sup>PX7138 (Scott Morton Trial Dep. at 66 (*in camera*)). Respondents also cite to witnesses who extol the value of Illumina's products—a fact that Complaint Counsel does not dispute—but this has no bearing on Illumina's treatment of its customers. For instance, Respondents quote Dr. Gao of Singlera who testified that "Illumina has paved the way for NGS," *see* Resp. Post-Tr. Br. at 113, but Dr. Gao also testified that Singlera was like a "prisoner of war" to Illumina. (CCFF ¶ 1174).



Second, even if there was a reputation to ruin, a diminishing reputation would have no impact on Illumina's NGS sales. As discussed extensively in Complaint Counsel's post-trial brief and *supra*, Illumina's NGS platforms are the only options for MCED test developers. *See, supra*,

§ II.B; CC Post-Tr. Br. § II.D.2; (CCFF ¶¶ 1019-1731). As Complaint Counsel's expert, Dr. Scott
Morton, testified, {
Perhaps the starkest (PX7138 (Scott Morton Trial Dep. at 66-67 (in camera)).
example of this is {
substantial fees, a loss of supply and support, threats against { } customers, and a denial
of critical rights for FDA approval. {
} has continued to develop its MCED test on
Illumina's NGS platforms because it has no other option. {

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. This means that if Illumina does disadvantage or foreclose its customers, only that customer (and Illumina) would ever know.<sup>80</sup> (CCFF ¶ 4934).

### D. Respondents' Claims About NGS Costs Are Immaterial to Illumina's Ability To Harm Grail's Rivals

Respondents offer several unsubstantiated theories in response to Complaint Counsel's *prima facie* case. They assert, by inference, that decreasing NGS costs over time eliminates Illumina's ability to harm Grail's rivals, despite overwhelming direct evidence to the contrary.

<sup>&</sup>lt;sup>80</sup> Moreover, Illumina has already shown that risk to reputation does not impact its business decisions. Illumina closed the Acquisition despite the European Commission's prohibition against doing so, acknowledging that this decision could result in "adverse consequences to, among other things, its reputation." (CCFF ¶ 219).

Respondents argue that some market participants expect NGS costs will constitute a small portion of MCED test revenues and margins, suggesting a constraint on Illumina's ability to harm its downstream rivals. Resp. Post-Tr. Br. at 121. Respondents' lack of theoretical support for this argument is best illustrated by their reliance on a single non sequitur within a textbook espousing a "radical interpretation of market power" under Australian competition law. This metric, however, is irrelevant. To the extent such information has any probative value, it suggests Illumina will have less incentive to maintain NGS sales to MCED test developers. Because Illumina stands to in the future, it will be less constrained in foreclosing Grail's rivals. Such information elucidates Illumina's desire to . See, supra, § III.C.1.

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 reflected in Respondents' own cited economic literature. *See* Carl Shapiro, *Testing Vertical Mergers for Input Foreclosure*, Organization for Economic Co-operation and Development 4 (2019) ("The first step [in the "ability and incentive" analysis] is to ask whether the upstream input involved in the merger is competitive significant to the downstream rivals that have been using that input. An input is

<sup>&</sup>lt;sup>81</sup> Respondents cite 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. Respondents' reliance on Rogerson is also misplaced. Respondents' 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.

competitive significant to a downstream rival if that firm's ability to compete with be substantially impaired if it were to lose access to the input."); see also Resp. Post-Tr. Br. at 108 (citing Dr. Shapiro's "Testing Vertical Mergers for Input Foreclosure" article). Here, the record is clear that Illumina will have the ability to disadvantage, or even completely foreclose, Grail's rivals of a critical input to MCED testing. (CCFF ¶ 2607-3078). Indeed, Complaint Counsel outlined in detail the various mechanisms through which Illumina can harm competition outside of price. See CC Post-Tr. Br. § II.E.1.a.ii (describing how Illumina can completely foreclose Grail's rivals, impact supply, diminish service and support, delay or deny access to new technology, develop products for Grail to the exclusion of rivals, or deny access to critical information and agreements for FDA approval). Respondents' myopic focus on NGS costs relative to MCED revenues ignores the degree to which MCED test developers rely on Illumina for aspects unrelated to pricing, though even Illumina's pricing remains unconstrained post-Acquisition. 82

Illumina's ability to harm Grail's rivals—and thereby harm competition—is based on the lack of NGS platform alternatives available to those rivals, not what percentage of MCED revenue and margins NGS costs encompass. The evidence that MCED test developers do not have alternatives to Illumina, and will not have alternatives for the foreseeable future, is overwhelming. (CCFF ¶ 1053-1398). Respondents suggest that Illumina's projected lower NGS costs "reflect powerful constraints" and are, at least in part, caused by future NGS platform competition for MCED testing. Resp. Post-Tr. Br. at 122-23 (highlighting vague statements from Illumina's executives for support). But lower NGS costs relative to total MCED testing margins do not

<sup>&</sup>lt;sup>82</sup> Illumina retains complete control over the pricing it provides to Grail, and the Open Offer fails to prevent Illumina from pricing in ways that disadvantage Grail's rivals. *See, infra*, § IV (outlining how Illumina can increase the NGS costs for Grail's rivals, even under the Open Offer).

warrant such an inference.<sup>83</sup> To the contrary, MCED test developers themselves unequivocally testified that they have no alternatives to Illumina's NGS platforms for MCED testing. (CCFF ¶¶ 1053-1200). A more plausible explanation for lower NGS costs in the future—and a fact that Respondents highlight in their briefing—is that Illumina lowers the cost of NGS platforms to expand total profits across all of its use cases. Resp. Post-Tr. Br. at 123 ("Dr. Febbo explained '[w]e have dropped the cost of sequencing through our investment in R&D . . . because in research what we saw is a term 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.""); see also (PX7145 (Katz) Dep. at 70) ("But to your question, why would a monopolist continue to reduce costs, I mean, I guess to the economic answer . . . is well, why wouldn't it? Reducing costs can be a benefit depending on how much it has to spend to reduce those costs, but lower costs can increase a monopolist's profits. So it has an incentive to try to lower its costs."). 84 Reading anything about competition into the price of NGS platforms at a particular time, without additional information or context, is a fool's errand betraying the sheer lack of direct evidence supporting the claim that Illumina is on the precipice of robust NGS competition for MCED testing. Respondents' spurious inferences are poor substitutes for evidence. That is particularly true when such inferences are at odds with the extensive ordinary course documents and testimony in the record, which clearly

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<sup>&</sup>lt;sup>83</sup> Indeed, elsewhere Respondents argue that Illumina has generally lowered its NGS costs historically. *See* Resp. Post-Tr. Br. at 113. Yet Illumina has yet to face meaningful competition from an NGS platform that meets the requirements of MCED tests. (CCFF ¶¶ 1019-1398). By Respondents' faulty logic, there would already be ample alternatives for MCED testing available today.

<sup>&</sup>lt;sup>84</sup> A monopolist innovating to lower the cost of a product to expand its total profits does not indicate it faces 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).

show MCED developers have no alternatives to Illumina now and for the foreseeable future. (CCFF ¶¶ 1053-1398).

### E. Respondents' Assertions of "Intensifying NGS Competition" Are Unsupported by the Record

#### 1. Purported NGS Alternatives Are Not Viable Substitutes to Illumina

As explained, supra, § II.B, Respondents' purported alternative NGS platforms are not viable substitutes to Illumina. Respondents offer unsupported theoretical arguments about (1) MCED investment and (2) Illumina's purchase price of Grail, drawing fact-free inferences about the effects of the Acquisition against the weight of the record. Accordingly, Respondents have failed to meet their burden to show timely, likely, and sufficient entry that would "fill the competitive void" left by the Acquisition. *H&R Block*, 833 F. Supp. 2d at 73 (D.D.C.).

#### 2. MCED Test Investment Activity Theory Is Untethered to Reality

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. As Dr. Scott Morton explained,

PX6091 (Scott Morton Rebuttal Report) ¶ 67).

Moreover, some of the MCED test developers receiving investment are developing products other

than MCED tests.
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,
Further, the FTC's investigation was non-public as was much of
the evidence presented in the ongoing litigation.
As such, investors are not aware of all the ways this Acquisition is anticompetitive.
Finally, the existence of some level of investment does not establish that, absent the Acquisition,
investment would not have been higher. (
RX6004 (Katz Trial Dep. at 75)).

Instead, 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").

#### 3. Grail Purchase Price Theory Is Economic Conjecture Without Factual Support

Respondents theorize that Illumina would not have paid \$8.3 billion for Grail if it already possessed the ability to extract most of the rents from Galleri. Resp. Post-Tr. Br. at 129.

Respondents argue that this theory undermines Complaint Counsel's case, notwithstanding the overwhelming evidence supporting Complaint Counsel's theory of harm. Resp. Post-Tr. Br. at 129. The sole basis for Respondents' argument is the conjecture of one of their economic experts, and thus their theory remains purely theoretical. They present no factual evidence—not even self-serving testimony from their executives—to establish the assumptions underlying their expert's reasoning. There is no evidence that Grail's purchase price is a large amount relative to the projected size of the MCED market, especially considering Illumina projected

(CCFF ¶¶ 480-81). 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-Tr. Br. 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, including Galleri, by then increasing the prices of the essential NGS platforms that it would sell to GRAIL." Resp. Post-Tr. Br. at 129. Instead, Illumina's ordinary course, pre-deal documents show that Illumina sought

(CCFF ¶¶ 483-84). The overwhelming record evidence contradicts Respondents' theory. Despite Respondents' characterization that their theory posits "real world facts," Resp. Post-Tr. Br. 130, they offer none.

Even setting aside the absence of any factual moorings to Respondents' theory, the theory itself is flawed. Respondents inappropriately assume the extreme case in which Illumina can

extract "most of the returns from Grail[]" without the Acquisition. Resp. Post-Tr. Br. at 129. As Dr. Scott Morton explained, under the widely accepted Nash Bargaining Model, Illumina and Grail are likely to divide returns from MCED test investment without the merger. (PX6090 (Scott Morton Report) ¶¶ 257-263); see also (PX7132 (Willig Dep. at 299-300) (describing Nash bargaining theory in which an upstream monopolist and a downstream monopolist will divide surplus equally between themselves)). But one does not need to rely solely on Dr. Scott Morton. Other economic models are consistent with Complaint Counsel's case. For example, a model created by Dr. Katz, Respondents' economic expert endorsing their purchase price theory, showed that even an upstream monopolist with "all the bargaining power" may be unable to extract the full returns from downstream investment. Benjamin E. Hermalin & Michael L. Katz, *Information* and the Hold-Up Problem, 40 RAND J. of Economics 3, 405, 406-07, 419-20 (Autumn 2009) (While "perfect information" may allow a seller being able to extract all rents from downstream investment, the article establishes that "anything can happen" in circumstances in which "the seller's information is imperfect": a "more realistic case."). Thus, setting aside that Respondents' argument is unsupported by any facts in this case, even in theory it is an edge case that is conceptually unrealistic.

## F. Respondents' Claims About Prior Vertical Integration Are Unsupported

Complaint Counsel has shown, through extensive ordinary course documents and testimony, that when Illumina has been vertically integrated in the past, its incentives towards its customers offering competitive products has changed. CC Post-Tr. Br. §§ II.E.1.a.ii.g; II.E.1.b.iii. While Respondents try to dismiss Illumina's own words, documents, and testimony, these prior "real-world instances of vertical integration" by Illumina, *see United States v. AT&T, Inc.*, 310 F.

Supp. 3d 161, 222 (D.D.C. 2018), help inform Illumina's likely actions towards its MCED test customers post-Acquisition.

## 1. Respondents Mischaracterize the Impact of Illumina's Vertical Integration in NIPT

Respondents argue that Illumina's acquisition of Verinata "brought increased competition, lower prices, increased output and enormous benefits to patients," Resp. Post-Tr. Br. at 134, but this argument is belied by ample pre-Acquisition evidence, as well as testimony from several fact witnesses. When ignoring the self-serving, biased testimony of Illumina's own executives, and the misleading representations Respondents make to this Court, the record shows that Illumina's vertical integration in NIPT gutted competition, forced low-price rivals to abandon the market, and harmed millions of patients. Indeed, Illumina's own documents reveal that Illumina's purpose for acquiring Verinata was not to increase competition, as Respondents claim, but rather to impose a

(CCFF ¶ 4124); (PX2076 at 003 (Illumina, Strategic Approach to Shaping the NIPT Market, Mar. 13, 2013)); (PX7060 (Naclerio (Illumina) IHT at 65)). While Respondents claim that "if Complaint Counsel's theory [of the case was] correct, then one would expect to see evidence of diminished competition following Illumina's entry," Resp. Post-Tr. Br. at 134, it is impossible to look at the actual record evidence and not see this evidence.

that would put a stop to

## a. When Vertically Integrated Illumina Imposed Fees on Its Low-Cost Competitors To Create a "Price Floor" for the Market

As Respondents admit, at the time that Illumina acquired Verinata, four companies provided NIPT in the United States: Sequenom, Verinata, Ariosa, and Natera. Resp. Post-Tr. Br. at 134; see also (CCFF ¶ 4103). Sequenom and Verinata used a sequencing technique that required

more of Illumina's core consumables per test, leading to higher costs, and higher revenue per test for Illumina. (CCFF ¶¶ 4108, 4111); (PX7089 (Naclerio (Illumina) Dep. at 129). Newer entrants Ariosa and \_\_\_\_\_\_, on the other hand, used an innovative method that significantly reduced the amount of Illumina's core consumables required per test, giving Illumina far less profit, but providing a lower cost to consumers. (CCFF ¶ 4115); {

With the lower cost, former Ariosa CEO Dr. Song testified that Ariosa was able to target a broader patient population than Sequenom and Verinata because its test was less expensive. (PX7071 (Song (Omniome) IHT at 69)). For example, Ariosa's test cost \$795 whereas Sequenom and Verinata "were pricing their tests at about \$2,700." (PX7071 (Song (Omniome) IHT at 69)). Illumina recognized the impact of these low-cost tests to its profitability, noting internally that "Ariosa is the worst and then Natera." (PX2296 (Email from T. Orpin, Illumina, to V. Vanier, Illumina, May 14, 2014)). 85

After Illumina completed its acquisition of Verinata, Illumina retained McKinsey & Co. to review its NIPT strategy. (PX7089 (Naclerio (Illumina) Dep. at 67-68)). McKinsey recommended that Illumina implement licensing strategy to ensure that "[m]arket prices will be protected in this environment because [a] licensing fee with partners will create a pricing floor." (PX2272 at 006 (E-mail from N. Naclerio, Illumina, to N. Donoghoe, McKinsey, Mar. 11, 2013)). Illumina and McKinsey then laid out a strategy to "[c]reate a cost structure for Natera that they

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<sup>&</sup>lt;sup>86</sup> Illumina's employees, under the direction of Nick Naclerio, Illumina's then-SVP of Corporate and Venture Development, collaborated with McKinsey on the project. (PX7089 (Naclerio (Illumina) Dep. at 90, 93)).

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."87

#### Proposed strategy in US Limit available licenses to Verinata, Ariosa, Sequenom, LabCorp, and Quest Announce that ensuring test quality will require a limited number of more well established NIPT providers Quickly secure cross-license with Sequenom to strengthen IP position with other parties Rapidly ensure Quest partnership with Illumina through either license (preferably) or send-out Get a revenue stream from LabCorp by licensing IP if possible, ultimately weakening Ariosa Create a cost structure for Natera that they can't sustain or introduces a reasonable price floor Lock in Ariosa to license terms in order to ensure Market price floor Solidify IP position amongst all NIPT players Lock up payor contracts (at a minimum, ensure Quest or LabCorp are included and drive Verinata inclusion in contracts over Ariosa & Sequenom)

(PX2076 at 003 (Illumina, Strategic approach to shaping the NIPT market, Mar. 13, 2013))

(emphasis added). {

When {

Illumina found additional ways to harm these customers. For example, when {

<sup>87</sup> This NIPT strategy was created under the guise of "ensuring test quality," which is exactly the rationale Illumina posed to this Court to justify { See, infra, § III.F.2; Resp. Post-Tr. Br. at 140.

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}	

Similarly, when Ariosa refused to pay the test fee, Illumina terminated its supply agreement with Ariosa, (PX7089 (Naclerio (Illumina) Dep. at 183)); (PX2242 at 003 (Email from C. Dadswell, Illumina, to C. Henry, Illumina, Apr. 25, 2014)), and sued Ariosa for IP infringement. (PX7060 (Naclerio (Illumina) IHT at 7)). As a result, Ariosa was forced to switch from running its test on NGS to running it on microarrays, "halt[ing] every single other development project" so that it could shift resources to changing its test.<sup>89</sup> (PX7071 (Song (Omniome) IHT at 91)); *see also* (PX7096 (Song (Omniome) Dep. at 29-30) (*in camera*)). At the time, Ariosa had the highest market share in NIPT and was considered { } by its competitors. ( } PX2274 at 006 (Strategic Approach to Increasing Value in NIPT Testing, Illumina, Mar. 20, 2013)).

<sup>88</sup> As a result of Illumina's actions, {

<sup>&</sup>lt;sup>89</sup> The halted projects included an innovative effort to combine NIPT with screening pregnant women for infectious disease that could impact the pregnancy. (PX7071 (Song (Omniome) IHT at 92-93)). Ariosa was unable to resume its work on this combination test because it not possible to perform the test on microarrays due to their lower sensitivity. (PX7071 (Song (Omniome) IHT at 93)). Ariosa was likewise forced to halt its work on detecting DiGeorge syndrome, a disorder where babies are born with significant cardiac defects that need to be treated immediately after birth. When DiGeorge syndrome is detected early, parents are able to "have the child delivered in a specialized center so that they can be taken care of immediately." (PX7071 (Song (Omniome) IHT at 92)). Ariosa

<b>b</b> .	After Vertically Integrating, Illumina Blocked Its Rivals From Developing NIPT
	IVD Tests

broadest possible population. (CCFF ¶¶ 4150, 4156).

<sup>&</sup>lt;sup>90</sup> As discussed in Complaint Counsel's post-trial brief, {

<sup>}</sup> Previously, Illumina

unsuccessfully attempted to obtain FDA approval for its NIPT test in 2014. (PX2571 at 009-020 (Illumina Inc. Diagnostics Committee Meeting, Jul. 30, 2014).

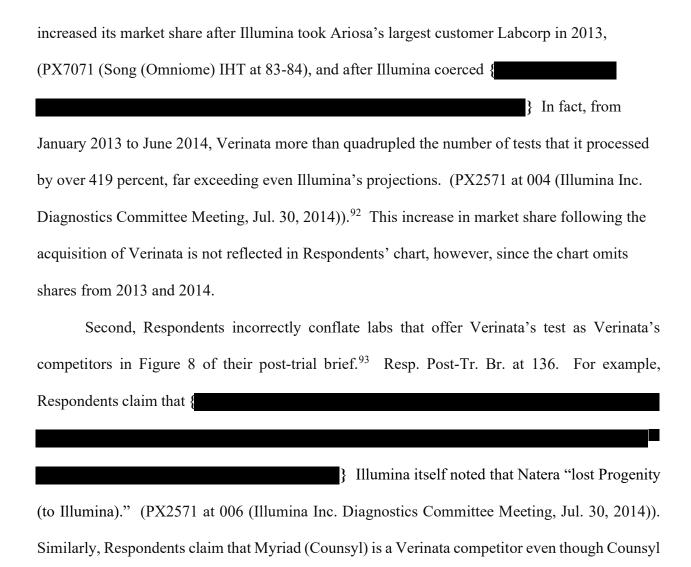
### c. Respondents Distort Data on NIPT Output and Market Shares

Respondents misleadingly claim that after Illumina acquired Verinata, "the number of NIPT tests conducted by Illumina's rivals on Illumina's platforms in the U.S. has increased in each year." Resp. Post-Tr. Br. at 134. Respondents' calculations, however, include companies such as Labcorp, Myriad, BioReference Laboratory, and Progenity as Illumina's "competitors" even though they actually use Illumina's NIPT test.

Respondents' analysis also does not include data from 2013 and 2014, the two years immediately following Illumina's acquisition of Verinata. (RX6000 (Carlton Trial Dep. at 148-49)). Moreover, even if the number of NIPT tests conducted by Verinata's rivals did increase, it increased *despite* the transaction, not

of NIPT tests conducted by Verinata's rivals did increase, it increased *despite* the transaction, not because of it, and the relevant inquiry would, instead, be to compare the number of tests performed today with the number of tests that *would have been performed* absent the Verinata acquisition. As was explained *supra* § III.F.1.a-b, rather than supporting rivals' growth, Illumina adopted a strategy of imposing costs, diminishing supply, or denying rights to Verinata's lower-priced competitors to prevent them from competing as aggressively in the market.

Respondents further claim that "[i]f Illumina had engaged in foreclosure following the Verinata acquisition, one would expect to see Verinata's share increase after the acquisition, but instead 'Verinata's share is going down." Resp. Post-Tr. Br. at 136. This is, once again, highly misleading and untrue. First, the chart Respondents include on shares of NIPT tests (Figure 8) again omits the first two years after Illumina acquired Verinata in 2013. (RX6000 (Carlton Trial Dep. at 148-49)) (claiming that he did not have data prior to 2015 that was comparable to the data after 2015). Unsurprisingly, in the two years following the acquisition, Verinata massively



<sup>91</sup> 

PX2274 at 006 (Strategic Approach to Increasing Value in NIPT Testing, Illumina, Mar. 20, 2013)). 
Ye At the time of Illumina's acquisition of Verinata, Illumina estimated that NIPT market shares were 40 percent Ariosa, 30 percent Natera, 20 percent Sequenom (and others), and 10 percent Verinata. (PX2274 at 006 (Strategic Approach to Increasing Value in NIPT Testing, Illumina, Mar. 20, 2013)). Respondents' Figure 8 shows that Verinata's share of tests had nearly quadrupled by 2015, inclusive of the Labcorp samples tested at Verinata's lab. Resp. Post-Tr. Br. at 136.

<sup>&</sup>lt;sup>94</sup> In addition, some of the "Progenity" tests that are included in Respondents' Figure 8 were actually run in Verinata's lab. *See* (PX2760 at 024 (Inside Sales Training NIPT, Illumina, 2016)) (including "Progenity" as one company sending tests out to Illumina's lab).

runs its tests in Illumina's lab. (PX2760 at 024 (Inside Sales Training NIPT, Illumina, 2016)). Correctly including these tests as "Verinata" only leaves Natera and Labcorp (Sequenom)<sup>95</sup> as independent NIPT competitors to Verinata, with Ariosa all but out of the market. This is fewer competitors than were present when Illumina acquired Verinata in 2013.<sup>96</sup>

Moreover, Respondents incorrectly claim that there has been a steady stream of new entry into NIPT. Resp. Post-Tr. Br. at 136-37. As was explained *supra* § III.F.1.a-b, Illumina has used its vertical integration in NIPT to prevent new entry, not to facilitate it. Respondents also misleadingly claim that Progenity and Quest "entered" with NIPT tests, neglecting to mention that Progenity was actually selling Verinata's test, and Quest was a Sequenom customer. *See* (PX2571 at 006 (Illumina Inc. Diagnostics Committee Meeting, Jul. 30, 2014)). Respondents also claim that Myriad (Counsyl) entered, even though Myriad's tests run in Verinata's lab, (PX2760 at 024 (Inside Sales Training NIPT, Illumina, 2016)), and that ARUP entered, {

Finally, Respondents misrepresent that Illumina's vertical integration in NIPT led to decreases in the cost of NIPT and an increase in payer adoption. Resp. Post-Tr. Br. at 138. Other than Respondents' biased and self-serving testimony of their own executives, Respondents' only support for this proposition is a declaration from Invitae, {

<sup>&</sup>lt;sup>95</sup> Respondents also misrepresent Labcorp as an independent Verinata competitor in 2015 and 2016, {

<sup>&</sup>lt;sup>96</sup> Although Quest is listed separately from Sequenom in Respondents' Figure 8, Quest actually runs Sequenom's test. (PX2571 at 004 (Illumina Inc. Diagnostics Committee Meeting, Jul. 30, 2014)); Resp. Post-Tr. Br. at 136.

}
integration did not increase payer adoption. {
(PX2428 at 024 (Project Positano, Illumina, Dec. 27, 2012)). Likewise, Illumina's vertical
improvements in throughput that would enable NIPT providers to run more samples per flow cell.
Verinata assumed that the cost of sequencing for NIPT would decrease dramatically due to
Illumina's acquisition of Verinata. For example, Illumina's analysis underlying its acquisition of
industry participants unequivocally shows that the cost of NIPT decreased independently of
By contrast, Respondents' own ordinary course documents and testimony from NIPT

As a result of Illumina's vertical integration in NIPT, millions of patients were likely harmed. As former Omniome Executive Chairman Ken Song testified, because of Illumina's acquisition of Verinata,

fewer women actually ended up getting tested, which ultimately translated into more unnecessary amniocenteses needing to be done, which ultimately led toward more fetal loss. . . . I think that is the price that society had to pay as a result of sort of all these shenanigans that happened post the acquisition of Verinata by Illumina.

(PX7071 (Song (Omniome) IHT at 11-12, 87-88)).

Illumina's vertical integration in NIPT did not catalyze new entry; on the contrary, it blocked new firms from entering the market and prevented existing firms from growing and

competing aggressively against Illumina. Illumina cannot claim that its acquisition of Verinata is an example of how its vertical integration is pro-competitive. Instead, it illustrates how Illumina uses its vertical integration to bolster its own bottom line, at the expense of innovation, competition, and consumers.

## 2. Illumina Considered Potential Cannibalization From Therapy Selection Test Customers When Evaluating Partnership Agreement

In direct contradiction to extensive ordinary course documents and testimony, Respondents argue that Illumina's vertical integration in therapy selection testing did not impact its behavior towards its therapy selection customers and, instead, Illumina allowed its customers to "flourish[] with investment and innovation." Resp. Post-Tr. Br. at 138-39. Respondents' flawed narrative, bolstered only by self-serving post-conduct testimony, relies heavily on the fact that Illumina eventually provided IVD agreements to its customers, regardless of any interim harm that took place in the preceding years. Specifically, Respondents claim that

Resp. Post-Tr. Br. at 140. These claims, however, fly in the face of Illumina's own pre-Acquisition documents and testimony revealing that Illumina

{

} Respondents do not,
and cannot, point to a single document that says otherwise. Moreover, Illumina's documents
seemingly recognize the competitive threat, {
} (CCFF ¶¶ 3779-82). Illumina recognized that granting IVD rights would
$\}^{100}$ and noted that $\{$
} (CCFF ¶ 3779).
Second, even if Respondents' claim is correct that Illumina {
} Illumina is admitting its
problematic role as the gatekeeper for which companies are allowed to compete against it in a
given market. Rather than let the free market determine whether {
} Illumina made that determination itself. Thus, {
Because MCED test developers rely on Illumina for the
development and commercialization of their tests, Illumina can similarly serve as the gatekeeper
for the MCED test market, substituting its own "judgment" for that of the free market.
100 (CCFF ¶ 4029)

With respect to Roche, Respondents argue that while {
Resp. Post-Tr. Br. at 141. Respondents' only
support for their claim is the post-Acquisition self-serving testimony of Illumina's own executives
and paid expert, 101 see (Response to RPFF ¶¶ 971.3, 971.3.1, 972.1), which should be given
"extremely limited" probative value. Bazaarvoice, 2014 WL 203966, at *73. Instead, the
overwhelming pre-Acquisition evidence shows that Illumina only decided that the benefits of an
IVD agreement with Roche {

<sup>&</sup>lt;sup>101</sup> While Respondents also cite to one Illumina document, the document does not refer at all to any

<sup>} (</sup>PX2287 (Illumina) at 8 (Illumina, Project

With no other support for their argument, Respondents falsely and
improperly attribute their own counsel's words to Complaint Counsel's expert, Fiona Scott
Morton. Specifically, Respondents misquote Dr. Scott Morton as testifying that {
Resp. Post-Tr. Br. at 142. This
quote was actually a question from Illumina's outside counsel. In response, Dr. Scott Morton
qualified the question by answering {
} (PX7138 (Scott Morton Tr. Dep. at 275).
While Respondents argue that Illumina's IVD program "spurs innovation," the evidence
clearly shows that Illumina has made every effort to use its control over IVD rights to impair its
customers' ability to innovate. Resp. Post-Tr. Br. 143-44. First, the substantial fees and royalties
that therapy selection customers must pay to Illumina in exchange for IVD rights diminishes their
ability to innovate in therapy selection. {
} While Illumina internally noted that the

As discussed *supra*, Illumina set these terms explicitly to account for the { and now has standardized these exorbitant terms as "market practice" to justify their use elsewhere, including in the Open Offer.

a profit-maximizing firm should, for it makes "sound business sense" for Illumina to maximize its

To be clear, Complaint Counsel is not arguing that Illumina is acting any differently than

# 3. Illumina Disadvantaged Its Population Genomics Customers When It Launched a Competing Product

Respondents argue, as a rebuttal to Complaint Counsel's case, that Illumina's formation of Helix, a population genomics company, demonstrates its inclination towards good behavior after it vertically integrates. Resp. Post-Tr. Br. at 145-46. Respondents argue that population genomics is an "analogous situation" to MCED testing without presenting any evidentiary support. Resp.

vertically integrated.

Post-Tr. Br. at 146. To the contrary, the record actually reflects Illumina's unwillingness to engage with population genomics customers after it launched a competing technology.

When Illumina formed Helix—a company that provided direct-to-consumer health tests— Illumina acted in ways to advantage Helix over Illumina's other population genomics customers. For example, { }. Illumina also impeded the ability of one of its population genomics customers, Ancestry, to use NGS for its tests. (CCFF ¶ 2648). In particular, as Ancestry "moved into health [testing]" and became a closer competitor with Helix, it became clear that Ancestry "should transition to an NGS platform because it provided [] better information and particularly better health information" than microarrays. (PX7077 (Chahine (Helio) Dep. at 71)); (Chahine (Helio) Tr. 1120 (in camera)). As Dr. Ken Chahine—who served as Ancestry's Executive Vice President—testified, { his May 30, 2017 email, Dr. Chahine told Illumina, "[w]e cannot be put in a situation where this is a deliberate strategy by Illumina to delay our transition to true NGS to give Helix an advantage." (PX2421 (Illumina) at 001 (Email from K. Chahine, Ancestry, to M. Van Oene, Illumina, May 30, 2017)); (Chahine (Helio) Tr. 1121-22 (in camera)); (PX7077 (Chahine (Helio) Dep. at 144-45)).

(Chehine (Helie) Dep. et 159)). Amosstru had sought everentees that it would be treated on more
(Chahine (Helio) Dep. at 158)). Ancestry had sought guarantees that it would be treated on par
with Helix in terms of pricing and access to technology, similar to a most-favored-nations
("MFN") clause, but was ignored. (PX2420 (Illumina) at 001 (Email from K. Chahine, Ancestry,
to M. Van Oene, Illumina, Nov. 15, 2017)); (PX7077 (Chahine (Helio) Dep. at 142-43)); (PX2421
(Illumina) at 001 (Email from K. Chahine, Ancestry, to M. Van Oene, Illumina, May 30, 2017)).
In October 2017, Dr. Chahine relayed concerns to Illumina that the "sense internally [at Ancestry]
was that we are being stonewalled and that Illumina is delaying in bad faith to allow Helix to raise
money We are off the rails; let's please work together to get this on track ASAP." (PX2424
(Illumina) at 001 (Email from K. Chahine, Ancestry, to M. Van Oene, Illumina, Oct. 26, 2017)).
Concurrently, internal Illumina communications indicate that {

} But once Helix's business pivoted away from competing with Ancestry,
"[Ancestry's] relationship with Illumina certainly improved." See (PX7077 (Chahine (Helio) Dep.
at 130). As Dr. Chahine testified at trial, {
}
4. Illumina's Pre-Spinoff Treatment of Grail Is Probative of Illumina's Post- Acquisition Behavior
Respondents ask this Court to ignore the special pricing and other benefits Illumina gave
Grail when Illumina controlled it prior to spinning it off. The crux of their argument is that
Illumina was not favoring Grail at the expense of competitors then because "[t]here were no
' 1 N D
rivals." Resp. Post-Tr. Br. at 147. That is factually incorrect. Exact began developing a blood-
based pan-cancer screening test as early as April 2009. (CCFF ¶ 1908).

That same year, Illumina began working on a pan-cancer test. (CCFF  $\P$  23).

In 2016, when Illumina formed Grail as a separate corporate entity and held a controlling stake, Illumina provided Grail with special pricing and other benefits. *See* (CCFF ¶¶ 29-30, 36). An Illumina contemporaneous analysis contradicts Respondents' argument that Illumina was not aware of how Grail would be positioned relative to competitors. (CCFF ¶ 36) (Grail is "uniquely positioned to pioneer this field . . . at depths that are cost prohibitive for others."). And later Illumina's executives would acknowledge how the spinoff of Grail "actually leveled the playing field" such that by June 2017 there were "70-plus players now in the liquid biopsy space." (CCFF ¶ 47, 55). As Illumina's CEO Francis deSouza explained to investors in 2017, "[w]e 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." (CCFF ¶ 59).

# IV. Complaint Counsel Thoroughly Analyzed and Properly Dismissed Respondents' Flawed Behavioral Remedy

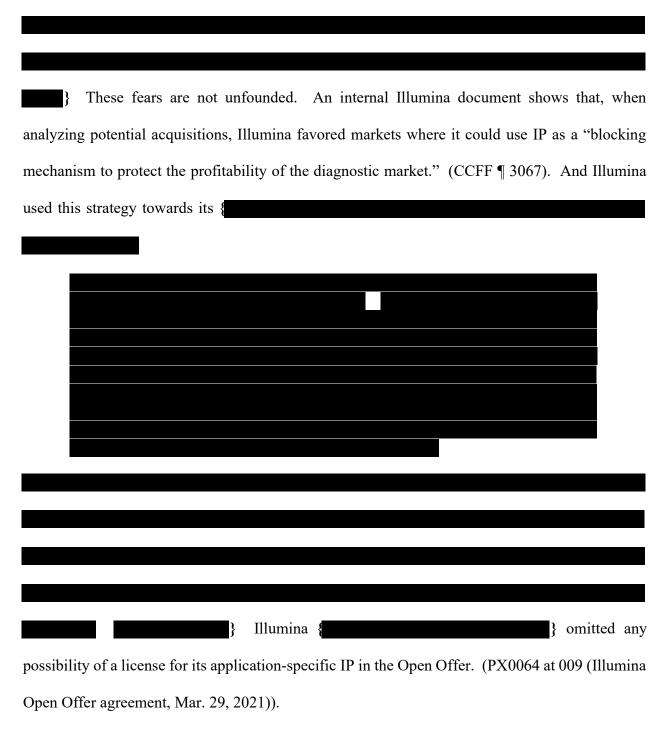
Respondents ask this Court to ignore all evidence of Illumina's clear ability and incentive to harm Grail's MCED rivals because, they argue, Illumina's non-negotiated, multipart supply agreement will remedy the illegal Acquisition. In support of their argument, Respondents offer only surface-level contentions that the Open Offer addresses every "lever" that Illumina could pull to disadvantage Grail's rivals, ensures Illumina is "incentivized to support customers' development of MCED tests," and "accounts for any possible anticompetitive effects." Resp. Post-

Tr. Br. at 148. In contrast, Complaint Counsel has fully detailed the myriad shortcomings of the Open Offer, including introducing evidence that each and every MCED test developer who testified about the Open Offer has concerns about its effectiveness. See CC Post-Tr. Br. at 159-80. Rather than address these shortcomings head-on, Respondents choose to miscite and misrepresent customer testimony as supporting the remedy, or else dismiss customers as "not credible" and "opportunistic," all while claiming to have generously incorporated their concerns into the Open Offer. But, as Respondents admit, the Open Offer is incomplete, its terms "flexible," and it has yet to be operationalized. Resp. Post-Tr. Br. at 153, 173. Thus, the Open Offer is far too speculative "for the court to evaluate its effects on future competition," Aetna, 240 F. Supp. 3d at 60, and the Open Offer's many flaws leave ample room for Illumina to act on its incentives to harm Grail's rivals to the benefit of Grail. See (CCFF ¶ 4177-79, 4184, 4191, 4468, 5008-10). Respondents have wholly failed to meet their burden to show that their behavioral remedy will restore competition lost from the Acquisition. See Otto Bock, 2019 WL 5957363, at \*44 (Respondents "bear the burden of showing that any proposed remedy would negate any anticompetitive effects of the merger[.]"); Staples, 190 F. Supp. 3d at 137 n.15.

# A. The Unilateral, Non-Negotiated Open Offer Fails To Allay Concerns About the Acquisition

Respondents argue that their unilateral Open Offer was designed to allay "[a]ny [c]oncerns" raised by any customers related to the Acquisition. Resp. Post-Tr. Br. at 149. Respondents would like this Court to believe Illumina is akin to a benevolent dictator, "committed to ensuring that its customers, including potential GRAIL rivals, are secure in their relationship

with Illumina post-merger." Resp. Post-Tr. Br. at 149. Respondents support this falsely
generous framing with self-serving testimony from their own executives and experts. Evidence
from Illumina's actual customers, however, shows that when crafting the Open Offer, Illumina
repeatedly ignored its customers' concerns. For example, {
} library preparation, one of the two primary types of
consumables that customers must purchase for their MCED tests. (CCFF ¶¶ 13, {
} the Open Offer provides no protections related to library preparation products.
(CCFF ¶¶ 4551-53).
Moreover, Illumina repeatedly refused to provide any pathway in its Open Offer for
customers to license Illumina's application-specific IP, which is {
} such as for the early detection of cancer. {
At the same time that Respondents claim generosity towards Illumina's customers, they also refer to them as "not credible," and "opportunistic," and refer to their concerns as "unreasonable demands," "exorbitant requests," and "gamesmanship." Resp. Post-Tr. Br. at 170-72. In addition, rather than working closely with customers to craft the Open Offer as Respondents claim, they instead {
(CCFF ¶¶ 3484, 3487). Respondents' strenuous attempts to pressure Illumina's customers into signing the Open Offer do not reveal the benevolent efforts of a company looking to reassure its customers, but instead expose the aggressive tactics of a critical supplier using out-of-court pressures to convince {
Respondents falsely claim that customers {
}



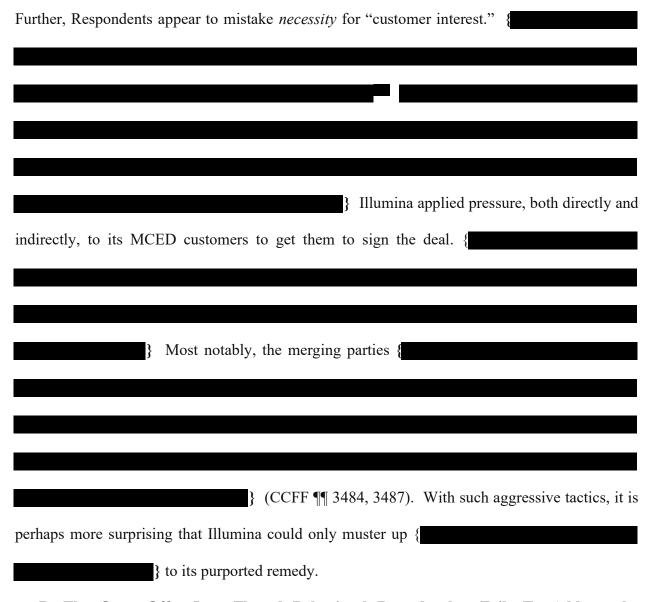
Despite significant outstanding customer concerns, Respondents falsely claim that the Open Offer was "satisfactory to customers" and "sufficient to resolve customer concerns with the Transaction." Resp. Post-Tr. Br. at 150. This is simply untrue. Not a single MCED test customer

who testified about the Open Offer, even those who have {
with Illumina, said that the Open Offer was sufficient to resolve their concerns. See, e.g., (CCFF
¶¶ 4993-5004); (PX7077 (Chahine (Helio) Dep. at 114-15); {
Moreover, a closer examination of Respondents' "support" for their claim
reveals that it is baseless and unsupported by record evidence. First, Respondents cite to the trial
testimony of { who never once, in his IH, deposition, or trial testimony,
testified that the Open Offer was satisfactory. {
} Second,
Respondents cite to { } to support their claim that Illumina's agreements
were "sufficient to resolve customer concerns with the Transaction," Resp. Post-Tr. Br. at 150, yet

	}	

Respondents also argue that the terms of the Open Offer "provide many customers benefits beyond those in the supply agreements entered into prior to the announcement of the Transaction." Resp. Post-Tr. Br. at 151. While Respondents put forth no evidence from Illumina customers to support their claims that the Open Offer provides additional benefits not otherwise available to customers, this is not the correct inquiry under the law. An acceptable remedy to an illegal acquisition cannot simply instill some benefit to the harmed market; it must "replac[e] the competitive intensity lost as a result of the merger." Aetna, 240 F. Supp. 3d at 60 (quoting Sysco, 113 F. Supp. 3d at 72) (emphasis in original). Post-Acquisition Illumina will have substantial ability and incentive to harm Grail's rivals; adding some new contractual language does not erase this ability or have any impact on this incentive. As Guardant's Getty testified, while certain provisions of Guardant's supply agreement with Illumina are helpful to Guardant, "it doesn't change the underlying premise of our analysis that the combined company would have the opportunity and incentives to advantage Grail in a competitive environment." (CCFF ¶ 4468). In addition, some customers testified that they were able to negotiate, at least at one point in time, better contractual terms than those available in the Open Offer. For example, {

} In
addition, at one point Illumina offered {
Post-Acquisition, however, Illumina changed course and {
} (CCFF
¶ 4396). The Open Offer only provides for a 17 percent discount for NovaSeq consumables at
annual spend of \$50 million and a 20 percent discount at an annual spend over \$75 million.
(PX0064 at 010 (Illumina Open Offer agreement, Mar. 29, 2021)).
Although Illumina unilaterally drafted the Open Offer, Respondents argue that the
"benefits and robust protections of the Open Offer are reflected by customer interest," particularly
by the fact that { Resp. Post-Tr. Br. at 152. As
discussed in Complaint Counsel's post-trial brief, only {
CC Post-Tr. Br. at 168
n.111, 180 n.119; see also (CCFF ¶¶ 1105, 4335, 4468). The other {
} either testified that they are not developing MCED tests in competition with
Grail, {
been identified as MCED test developers and never testified or provided evidence in this matter. 104
104 { did not testify or provide any evidence
in this matter.



# B. The Open Offer Is a Flawed Behavioral Remedy that Fails To Address the Competitive Concerns of the Acquisition

Respondents claim that courts "frequently find proposed remedies like the Open Offer sufficient to address the alleged anticompetitive harms." Resp. Post-Tr. Br. at 153. As an initial matter, because a remedy to a Section 7 violation must "restore the competitive intensity" lost

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from the acquisition, an appropriate remedy depends on the precise harms alleged. *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72). As the Supreme Court has explained, divestiture is the "most important of antitrust remedies," and it "should always be in the forefront of a court's mind when a violation of § 7 has been found." *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 330-31 (1961) [hereinafter "*du Pont 1961*"]. "[I]n Government actions divestiture is the preferred remedy for an illegal merger or acquisition." *California v. Am. Stores Co.*, 495 U.S. 271, 280-81 (1990). In contrast, behavioral remedies, like the Open Offer, are "disfavored," *Steves & Sons*, 988 F.3d at 720, and accordingly "are inappropriate except in very narrow circumstances." U.S. Dep't of Justice, Merger Remedies Manual (2020) § II [hereinafter "DOJ Merger Remedies Manual"]. Moreover, once the government has carried its burden as to liability, "all doubts as to the remedy are to be resolved in its favor." *St. Alphonsus Med. Ctr. - Nampa, Inc. v. St. Luke's Health Sys.*, 778 F.3d 775, 793 (9th Cir. 2015) (quoting *du Pont 1961*, 366 U.S. at 334) (internal quotation marks omitted).

The appropriateness of a behavioral remedy must be determined in light of the specific competitive harms at issue—not based on remedies from other unrelated illegal mergers. Even so, Respondents fail to point to any court that has endorsed a complex behavioral remedy of this kind. Instead, Respondents confusingly cite to three cases ordering or approving *divestitures* in support of their claim. *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 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.

Respondents only identify two cases involving non-structural remedies—*United States v. AT&T, Inc.* 916 F.3d 1029 (D.C. Cir. 2019) and *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285 (W.D. Mich. 1996)—and both cases involve entirely different facts, entirely different alleged harm, and are inapposite to the appropriate remedy here. 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 1045-46 (D.C. Cir.) (reiterating that the theory of harm was limited to consumer price effects). The district court referred to the Government's theory of harm as "a matter of first impression." *AT&T*, 310 F. Supp. 3d at 199 (D.D.C). 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 (D.C. Cir.).

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. 3d at 184, 200 (D.D.C.). Here, in contrast, Illumina's MCED customers will not know in real time, if ever, whether Illumina breaches the terms of the Open Offer.  $^{106}$  (CCFF  $\P$  4826-40).

<sup>&</sup>lt;sup>106</sup> Even if customers believe that Illumina may have breached its commitments, customers can only invoke an audit if they have a "good-faith basis" that Illumina violated the Open Offer, and *Illumina* determines whether there is such a basis. (CCFF ¶¶ 4817-18). And, once customers decide to initiate arbitration, they must wait 30 days to do so. (PX0064 at 010 (Illumina Open Offer agreement, Mar. 29, 2021)).

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. Here, even if Illumina's customers discovered a potential breach and engaged in the 120-day arbitration process, (CCFF ¶ 4814), the anticompetitive harm at issue would have already occurred, and such harm could not be "stayed" during the arbitration process or erased by any ultimate relief. 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 at ¶ 38, United States v. Comcast Corp., No. 1:11-cv-00106 (D.D.C. 2011) ("video programming distribution"), with AT&T, 310 F. Supp. 3d at 195 (D.D.C.) ("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. Further, the real-world evidence that does exist shows that, when vertically integrated, Illumina has acted in ways to harm its competitors and has failed to uphold its commitments. See, e.g., CC Post-Tr. Br. §§ II.E.1.a.ii.g, II.E.1.b.iii; {

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<sup>&</sup>lt;sup>107</sup> For example, if Illumina were to provide Grail with early access to a new NGS platform, by the time the breach was discovered (if it was) and arbitration concluded, Grail would have already had a significant advantage over its competitors that could not be undone. *See* (CCFF ¶ 5010) {

 $<sup>\</sup>$  (CCFF ¶ 4940) (Guardant's Getty testifying that by the time an arbitrator makes a decision, Illumina and Grail would have "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").

The proposed remedy in *Butterworth*, whose premise and holding has been cast into serious doubt by other courts, <sup>108</sup> is also 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

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<sup>&</sup>lt;sup>108</sup> Other courts have rejected the *Butterworth* premise that "nonprofit hospitals operate differently" than profit-maximizing hospitals. *See, e.g., United States v. Rockford Mem'l Corp.*, 898 F.2d 1278, 1285 (7th Cir. 1990); *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1213-14 (11th Cir. 1991); *FTC v. ProMedica Health Sys.*, 2011 WL 1219281 (N.D. Ohio 2011); *FTC v. OSF Healthcare Sys.*, 852 F. Supp. 2d 1069, 1081-82 (N.D. Ill. 2012). \*60

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, Illumina has ample tools to diminish MCED competition beyond just price—including impacting supply, diminishing service and support, delaying or denying access to new technology, or denying critical FDA agreements to MCED developers—which will harm innovation and choice in the MCED test market. *See* CC Post-Tr. Br. at 97-109.

Unable to ground the Open Offer in caselaw, Respondents proceed to argue that "the Open Offer addresses, point-by-point, each of the foreclosure concerns raised by Complaint Counsel and customers" and list in detail the various provisions of the Open Offer as if their mere existence remedies the Acquisition's harms. Resp. Post-Tr. Br. at 154-70. As Complaint Counsel explained at length in its post-trial briefing, each of these provisions has serious problems in implementation that allow for continued opportunity for Respondents to disadvantage Grail's rivals. CC Post-Tr. Br. § II.F.3.b.

Additionally, even *assuming arguendo* that the provisions provided some limitation on Illumina's ability to disadvantage rival MCED test developers, the provisions' effectiveness also depends on whether Respondents will actually abide by the terms of the Open Offer. Illumina asks this Court to trust that they will. But Illumina has continued to show that it is not logical to assume that Illumina, as a profit-maximizing firm, will act counter to its financial incentives. *See, e.g.*, (CCFF ¶ 220-21, 4491, 4746, 4985). While Complaint Counsel's extensive analysis of the Open Offer's flaws need not be repeated here, Respondents make a number of factual misstatements and baseless claims that must be addressed.

First, Respondents claim that the Open Offer's pricing provisions provide that "[t]o the extent Illumina offers more favorable pricing to GRAIL or any For-Profit Entity, it must promptly notify other Open Offer customers [and] make the more favorable pricing available to them." Resp. Post-Tr. Br. at 161. The unreliability of this claim, and of the Open Offer's pricing terms, becomes clear when viewing it in conjunction with Respondents' EDM efficiency claims. Specifically, Respondents argue that the Acquisition will allow the merged firm to eliminate the upstream margin that Illumina currently charges to Grail. *See* Resp. Post-Tr. Br. at 211-15. Should Respondents fully realize this efficiency, as they contend, this would mean that Illumina is providing its products to Grail *at cost*. The Open Offer, however, does not provide that Illumina will sell its products at cost to MCED test developers, and Respondents' expert admitted as much. *See* (CCFF ¶ 4634) (Dr. Carlton testifying that it "is not my understanding" that Illumina will provide its products Grail's rivals at cost). Accordingly, either the Acquisition will not lead to the EDM efficiencies that Respondents claim, or the Open Offer pricing provisions are meaningless.

Second, Respondents falsely claim that the Open Offer "expressly" provides that "any discretionary discounts offered to GRAIL . . . must be made available to all other Open Offer customers." Resp. Post-Tr. Br. at 161. In fact, Illumina *excludes* from the Open Offer these discretionary discounts. While pre-Acquisition, Illumina's sales team had discretion to provide customers with discretionary discounts in the ordinary course of business, *see* (CCFF ¶ 2725-43), post-Acquisition (pursuant to the Open Offer) Illumina can only provide such discounts under narrow circumstances. As Illumina executive Nicole Berry, the signatory of the Open Offer, admitted at trial, under the Open Offer customers "would not be eligible for discretionary pricing" unless the discount is given pursuant to the "Special Projects" provision of the Open Offer,

meaning for activities *outside* of the ordinary course of business. (Berry (Illumina) Tr. at 925). This change effectively increases customer pricing relative to the pre-Acquisition world. 109 Moreover, while Respondents cite to an Illumina executive and a paid expert for their false claims that any discretionary discounts offered to Grail must also be given to other Open Offer customers, a plain reading of the applicable terms provides only 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 008 (Illumina Open Offer agreement, Mar. 29, 2021)). "Volume-Based Net Price" means the list price of a product minus "the applicable discount for a customer's volume under a volume-based discount table." (PX0064 at 005 (Illumina Open Offer agreement, Mar. 29, 2021)) (emphasis added). Based on the plain language of the agreement, these provisions limit customers to receiving the same volume-based discounts as Grail and other equivalent customers; customers will not receive the same discretionary discounts, } (CCFF ¶¶ 2733, 2735). Nor would it be possible to make discretionary discounts equivalent across all customers because discretionary discounts are for { { (CCFF ¶ 2735). Accordingly, discretionary discounts are yet another tool Illumina can use to favor Grail over its rivals. 110

 $<sup>^{109}</sup>$  As Berry testified, discretionary discounts determine the "ultimate[] price the customer pays," (CCFF ¶ 4643), so removing these regular discounts would lead to relatively higher prices for customers.

<sup>110</sup> Respondents misleadingly cite the CEOs of Invitae and Helio as endorsing the pricing provisions of the Open Offer, alleging that they testified that "the MFN provisions have succeeded in helping to alleviate customers' concerns with the transactions." Resp. Post-Tr. Br. at 161. Both CEOs, however, testified that they are mostly unfamiliar with the MFN provisions in the Open Offer and are unsure how they would work in practice. (PX7081 (George (Invitae) Dep. at 60-61)); (PX7077 (Chahine (Helio) Dep. at 114-15)). Moreover, the evidence is clear that because Illumina now owns Grail, any Grail pricing is merely a fiction. *See* (CCFF ¶¶ 4383, 4634, 4638).

Third, Respondents mislead the Court by claiming that the Open Offer commits Illumina "to at least a 43% reduction in the price of sequencing by 2025." Resp. Post-Tr. Br. at 163. Despite the tricky terminology that Respondents choose, the Open Offer does not actually guarantee a meaningful price reduction of any sort to customers such as MCED test developers who are sequencing an extremely high number of short cfDNA fragments for their tests. The Open Offer provides that Illumina will reduce the price 43 percent per gigabase of sequencing, but does not address the price per read, which is the critical driver of per-sample costs for MCED test developers. (PX0064 at 007 (Illumina Open Offer agreement, Mar. 29, 2021)); see also supra, § II.B.1. The reason that price *per read* drives an MCED test developer's cost per patient sample is that MCED tests must read many millions of short DNA fragments from each patient's blood plasma sample. See (CCFF ¶ 937) { }. Critically, price per gigabase does not necessarily correlate with price per read, so promising a reduction in price per gigabase does not guarantee a reduction in price per read. For example, { the price per gigabase does not necessarily correlate with price per read.

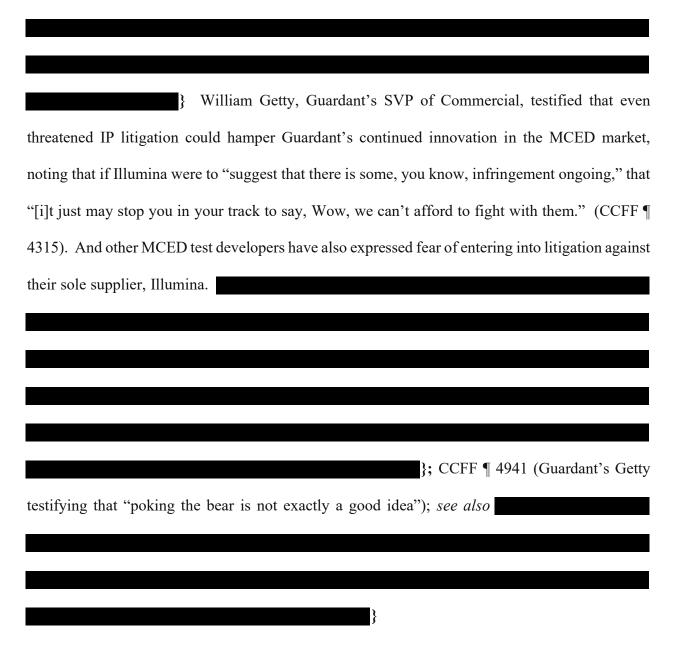
This means that the Open Offer's promise to reduce the price of sequencing by 43 percent per gigabase not only does not guarantee a corresponding 43 percent reduction in price per read, but in fact does not guarantee any reduction in price per read, or even guarantee that there will not be an *increase* in price per read, which is what matters to MCED test developers.<sup>111</sup>

Finally, Respondents argue that "Illumina cannot use IP litigation or threatened IP litigation as a guise for foreclosing GRAIL's putative rivals." Resp. Post-Tr. Br. at 167. Respondents appear to base this on the fact that the Open Offer provides that Illumina will not "cease shipments . . . solely on the basis of a claim of infringement of Illumina's intellectual property rights." (RPFF ¶ 1037). Post-Acquisition harm, however, goes beyond simply ceasing supply. While Respondents tout the Open Offer's arbitration provision, Illumina expressly carves out of this provision "claims involving infringement, validity, or enforceability of Intellectual Property Rights . . . or about the scope of Intellectual Property Rights." (PX0064 at 008 (Illumina Open Offer agreement, Mar. 29, 2021)). This means that if there is a dispute relating to intellectual property, Illumina can drag its customers through lengthy and costly IP litigation. And Illumina has already shown that it is willing to do this, suing Guardant in federal court for IP infringement, see Complaint, Illumina, Inc. v. Guardant Health, Inc., et. al., No. 1:22-cv-00334 (D. Del. Mar. 17, 2022), {

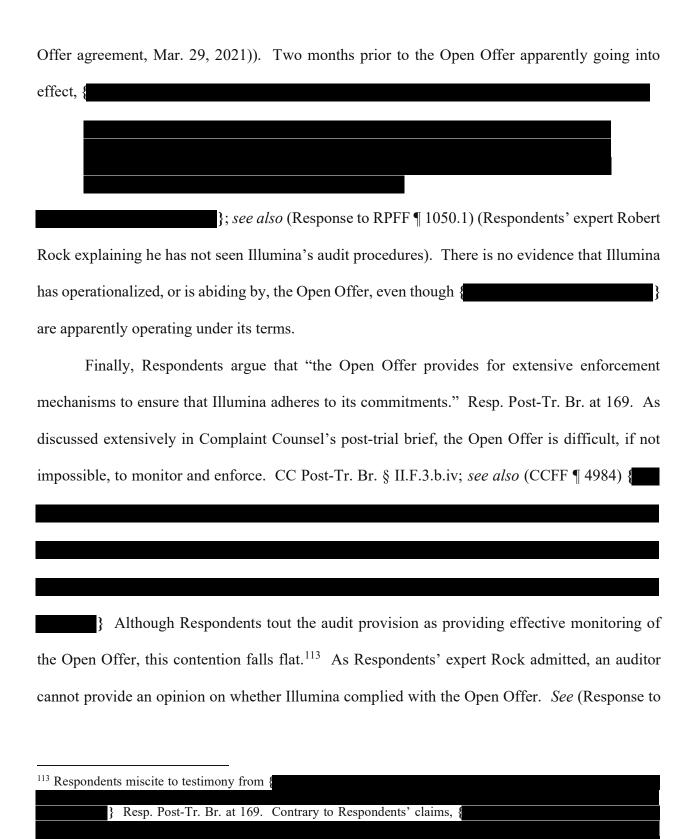
<sup>&</sup>lt;sup>111</sup> It is frankly uncertain, and entirely in Illumina's control, how much the price of sequencing ultimately changes for MCED test developers. While fixing prices as part of a remedy, in place of a free market, is always dangerous, this level of uncertainty makes the remedy too speculative "for the court to evaluate its effects on future competition." *Aetna*, 240 F. Supp. 3d at 60.

<sup>112</sup> Illumina has a reputation of using IP litigation as a sword, whether or not its IP claims have merit, to entrench its dominance in various markets. As Ken Song of Omniome (and previously of NIPT company Ariosa) testified, "I believe they literally use their IP as a weapon to try and control the marketplace." (CCFF ¶ 4986); see also {

And, even if Illumina cannot threaten or engage in IP litigation with its customers (which it can), Illumina has found other methods to use IP to hinder its competitors. {



In addition to Respondents' misrepresentations about their own proposed remedy, Respondents admit that they have yet to operationalize certain provisions of the Open Offer, even though the Open Offer became effective at the time the Acquisition closed on August 18, 2021, prior to trial. *See* (Op. Stmt. (Illumina) Tr. 84-85); (CCFF ¶ 200); (PX0064 at 003 (Illumina Open



RPFF ¶ 2027). And he added that the effectiveness of an audit depends on the specific procedures put in place, but he has seen no such procedures implemented by Illumina. *See* (Response to RPFF ¶ 2027). In addition, while Respondents claim that the audit provision provides that "if a customer has a good-faith basis for alleging that Illumina has breached the Open Offer, Illumina must engage an auditor to assess the allegation, separate from the biannual audits," Resp. Post-Tr. Br. at 169, Respondents ignore that Illumina executive Nicole Berry, the signatory of the Open Offer, admitted at trial that *Illumina* gets to decide whether a customer has a good-faith basis for alleging that Illumina is in breach. (CCFF ¶ 4818); *see also* {

Berry concedes, though, that customers will not know what prices its competitors are paying, what products its competitors have access to, or what level of service its competitors are getting to even know whether there is a potential breach. (CCFF ¶¶ 4826-28). And even if customers could detect a potential breach, Illumina could singlehandedly prevent any subsequent investigation.

In conjunction with the audit provision, Respondents argue that the arbitration provision of the Open Offer "help[s] guarantee that the Open Offer 'will have real-world effects' and put Illumina's 'money where [its] mouth is.'" Resp. Post-Tr. Br. at 169-70 (quoting *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018)). While this quote makes little sense in the context of the Acquisition, as discussed *supra*, the comparison to the arbitration provision in *AT&T* is inapposite. The arbitration provision of the Open Offer does not prevent, stop, stay, or erase any harm that Illumina imposes on its customers. Instead, even if a breach is discovered and the arbitration is successful, Illumina can still reap the rewards of its anticompetitive conduct. *See* 



Getty testifying that by the time an arbitrator makes a decision, Illumina and Grail would have "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"). And, far from putting its "money where its mouth is," Illumina has ensured that any such arbitration proceeding is confidential, *see* (CCFF ¶ 4934), so aside from a potential award that cannot actually alleviate the competitive harm, Illumina will face no additional consequences of a breach such as reputational harm or follow-on arbitration proceedings.

- C. Overwhelming Evidence Supports the Inability of the Open Offer To Restore Competition Lost From the Acquisition
  - 1. Illumina's MCED Test Customers Have Raised Consistent and Credible Concerns About the Open Offer's Efficacy

While in one breath, Illumina claims that it worked to allay all customer concerns and to ensure that its customers feel secure in their relationship with Illumina, in the next breath Illumina calls any customer who has raised concerns about the Open Offer "not credible," and "opportunistic," and refers to their concerns as "unreasonable demands," "exorbitant requests," and "gamesmanship." Resp. Post-Tr. Br. at 170-72. This disparagement of Grail's competitors is nothing new and, in fact, is part of a carefully crafted {

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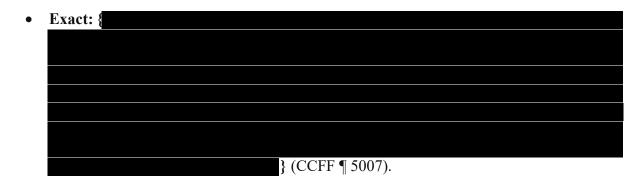
flaws in the Open Offer as complaints "from customers who intend to use the FTC investigation to pressure Illumina into accepting unreasonable demands." Resp. Post-Tr. Br. at 171; *see also* (PX4473 (Grail) at 003 (Core Team, Apr. 15, 2021) (*in camera*)). Respondents have attempted to

One of the specific goals {

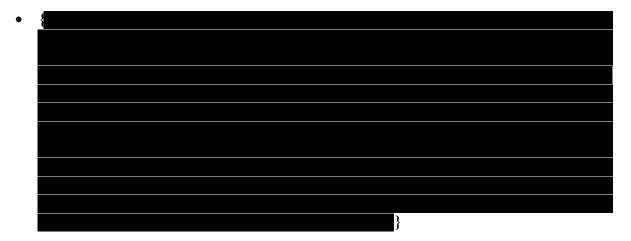
(PX4473 (Grail) at 003 (Core Team, Apr. 15, 2021) (in camera)). These attempts to use {

(PX4473 (Grail) at 003 (Core Team, Apr. 3) to discredit Illumina's customers expose the unreliability of Respondents' accusations and why Respondents' criticisms of its MCED customers should be disregarded.

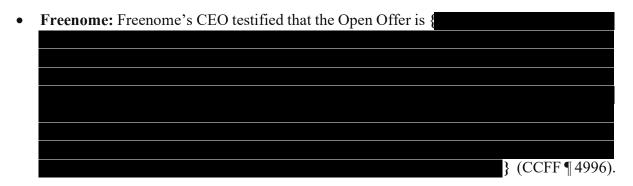
Respondents also claim that Complaint Counsel has "cherry picked" customer complaints and can only "muster up threadbare criticisms of the Open Offer's provisions," Resp. Post-Tr. Br. at 170, 172, when in fact every MCED customer who testified about the Open Offer criticized it for failing to resolve the competitive harm from the Acquisition:



}



• Guardant: Guardant's SVP of Commercial testified that, despite signing a long-term supply agreement with Illumina, he has several concerns about the agreement, including lack of insight into Grail's prices, inability to monitor whether Guardant is getting new technology at the same time as Grail, and a lack of an enforceable firewall. (CCFF ¶ 4468). He added, "the 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," although "[u]ltimately, . . . we don't have an option." (CCFF ¶ 4993).



• **Helio:** Former CEO of Helio Ken Chahine testified about the deficiencies of the pricing provisions in the Open Offer, explaining that "I don't understand how MFN [pricing provisions] would work in this context. Typically, it's a third party that you've given a price to that you've agreed that you would not give someone else a better price for." "[I am] having a little bit of a hard time understanding exactly how that construct contract would work," adding that "Illumina would be Grail, so I don't know what giving Grail a price actually means in this context." (PX7077 (Chahine (Helio), Dep. at 114-15)).



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o	om being "cherry-picked," these concerns reveal a consistent and widespread	sentiment (	0

Far from being "cherry-picked," these concerns reveal a consistent and widespread sentiment of the Open Offer's deficiencies from the customers that would be subject to its terms.

Despite the universal skepticism of the effectiveness of an Illumina-crafted remedy, Respondents want this Court to dismiss these complaints in part because "[m]any of the Open Offer's critics are barely even familiar with its terms," specifically identifying Exact's Conroy and Resp. Post-Tr. Br. at 170. While Conroy testified that he had discussed the Open Offer with counsel, but had not read it in detail himself, see (Conroy (Exact) Tr. 1725-27),  $\{(CCFF \P 4358, 4368-97).\ Moreover, \}$ contrary to Respondents' claims, {

Respondents also cast aside customers' negotiations as "exorbitant requests that clearly evidenced gamesmanship." Resp. Post-Tr. Br. at 171. Specifically, Respondents highlight

Resp Post-Tr. Br. at 171. As discussed *supra*, several

customers, including {
} from the early stages of negotiations with Illumina, well before the Commission issued
its Complaint in this matter. {
4347). Illumina had indicated to its customers during negotiations that {
} (CCFF ¶¶ 3070, 4190). In addition, Respondents argue
that {
opportunistic use of the FTC scrutiny to exert negotiating pressure on Illumina." Resp. Post-Tr.
Br. 172. Respondents ignore, however, that Illumina's own executive admitted that {
Because Illumina itself has asserted that its costs would decrease
six-fold in the next few years, (CCFF ¶¶ 4659-60), {
} Illumina chose not to
negotiate with its customers and opted instead to universally impose a self-serving contract, even

though negotiations like those from { a supplier-customer relationship. (Berry (Illumina) Tr. at 926). It is perhaps unsurprising, though, that Illumina mischaracterizes negotiation as coercion, as Illumina has no need to negotiate with customers who have no other alternatives. (CCFF ¶ 1139, 2715, 2718-19).

## 2. Respondents' Alleged Theory of Incomplete Contracting Fails To Immunize the Flaws of the Open Offer

While Complaint Counsel has detailed the various levers that Illumina can use to disadvantage Grail's rivals post-Acquisition, *see* CC Post-Tr. Br. § II.E.1.a, given the innovative industry and increasing reliance of MCED test developers on Illumina, it is impossible to predict all the ways, now and in the future, that Illumina can harm its customers. Thus, crafting contractual provisions today that will protect against competitive harms over the next 12 years is difficult, if not impossible, to do. In spite of this, Respondents argue that the theory of incomplete contracting somehow absolves them from all of the potential loopholes in the Open Offer. Specifically, they claim that "[t]he theory of incomplete contracting holds that, even though parties to a contract may not be able to foresee every possible circumstance that might arise during the life of a contract, parties can still create effective contracts and economists can still evaluate those contracts to determine whether they adequately address the parties' goals." Resp. Post-Tr. Br. at 173. Although incomplete contracting is an economic theory, Respondents cite to no studies or articles consistent with their interpretation of that theory. Rather, an explanation of this theory from economic literature provides:

Contracts are meant to protect people by aligning incentives. When contracts are incomplete, the alignment can be imperfect. Contracts can also be seen as a mechanism to achieve binding commitments that the parties can bank on in their

<sup>115</sup> Inexplicably, Respondents' only apparent support for its theory relates to {

See (Response to RPFF ¶¶ 1075-1075.3).

planning. When contracts are incomplete and imperfect, however, they have only *limited effectiveness* for achieving commitment.

Paul Milgrom and John Roberts, Economics, Organization, and Management 133 (1992) (emphasis added). While Respondents do not explain what they deem an "effective" agreement, a remedy to an illegal acquisition should restore competition, and the "limited effectiveness" of an incomplete contract would fail to do so. 116 See In re ProMedica Health Sys., Inc., 2012 WL 1155392, at \*48-50 (F.T.C. Mar. 28, 2012). It is precisely for this reason that courts have found that "once a merger is found illegal, an undoing of the acquisition is the natural remedy." Otto Bock, 2019 WL 5957363, at \*43 (quoting du Pont 1961, 366 U.S. at 329) (internal quotations omitted). Unlike an incomplete contract, divestiture is "simple, relatively easy to administer, and sure." Otto Bock, 2019 WL 5957363, at \*44 (quoting du Pont 1961, 366 U.S. at 330). Moreover, here the Court does not need to look to economists to "evaluate those contracts to determine whether they adequately address the parties' goals" because the actual parties to the contract (the MCED test developers) have already testified that the Open Offer does not address their concerns. See CC Post-Tr. Br. § II.F.3.b.v. While Respondents rely solely on their own experts to extol the benefits of the Open Offer, the actual customers who would be subject to its terms have testified otherwise.

Furthermore, Respondents' reliance on their theory of incomplete contracting directly contradicts Respondents' claims, in this same brief, that "the Open Offer accounts for and prevents all foreseeable circumstances" in which Illumina could harm Grail's rivals, and "the Open Offer

<sup>&</sup>lt;sup>116</sup> Sanctioning "incomplete contracts" as adequate remedies to illegal mergers would create a problematic standard that would, in essence, excuse any flaws of behavioral remedies as inevitable, failing to restore the competitive intensity lost through the merger.

completely addresses the competitive concerns that would likely arise over a twelve-year term."<sup>117</sup> Resp. Post-Tr. Br. at 159, 173 (emphases added). It is unclear whether Respondents view the Open Offer as perfect, or as inherently flawed, but any "incompleteness" or deficiencies in the Open Offer wrongly put the risk of a failed remedy squarely onto Illumina's customers and, ultimately, consumers. See Otto Bock, 2019 WL 5957363, at \*142 (explaining that "we aim to avoid placing the risk of a failed remedy on consumers"); see also Bigelow v. RKO Radio Pictures, Inc., 327 U.S. 251, 265 (1946) ("The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created."); Associated General Contractors v. Cal. State Council of Carpenters, 459 U.S. 519, 552 (1983) (same). As the Department of Justice's 2020 Merger Remedies Manual explains, "[r]emedies should be designed to limit the risk of failure as much as possible. To the extent any risk of failure remains, that risk should be borne by the parties, who seek to consummate a merger that would otherwise violate Section 7. Consumers should not bear the risk of a failed remedy." DOJ Merger Remedies Manual § II. Given the flawed provisions of the Open Offer, Illumina's incentive to circumvent its terms, and the difficulty of monitoring and enforcing it in a way that could actually avoid competitive harm, Illumina's customers will have to bear the risks of any failure of the remedy to protect competition in the research, development, and commercialization of MCED tests.

Respondents, however, choose to double down on their argument, claiming that while customers are concerned about the Open Offer, "these same customers enter into contracts all the

Respondents cannot fairly claim that the Open Offer's terms resolve all concerns when, in the middle of trial, Respondents revised the Open Offer to add new provisions. (CCFF ¶4483). The continuous changes to the proposed remedy that Respondents have made from the time Illumina sent its letters of intent to customers when the Acquisition was announced to the latest round of revisions show how difficult it is to craft a unilateral, long-term behavioral remedy that can actually restore pre-Acquisition competition. *See* (CCFF ¶¶ 4951-4973).

time." Resp. Post-Tr. Br. at 173. This is beside the point. The Open Offer is not a typical contract entered into in the ordinary course of business. Illumina is not negotiating with its customers on an arms' length basis and the Open Offer is not a bargained-for agreement between two parties to create value for both. Instead, Respondents are putting forward the Open Offer as its proposed *remedy* for its illegal Acquisition, and absent a divestiture, all MCED test developers will have to abide by the terms. As discussed *supra*, some MCED customers, like { } } had previously been negotiating with Illumina additional terms beyond what is in the Open Offer. With the remedy in place, however, customers like { } } can no longer negotiate for contractual terms to fit their own business needs; they must accept the contract that Illumina created and imposed on their behalf.

## 3. The Open Offer Does Not and Cannot Change Illumina's Incentives To Favor Grail

Respondents argue that it does not matter whether the Open Offer effectively curbs Illumina's incentives to harm Grail's rivals because the Open Offer "removes any ability for Illumina to meaningfully disadvantage" MCED test developers. Resp. Post-Tr. Br. at 174. But as Respondents admit, contracts are inherently flawed, and there is no way for a contract, to address every way in which Illumina can harm its customers. Resp. Post-Tr. Br. at 173. Respondents have admitted that certain terms in the Open Offer are "flexible," and that Illumina has yet to operationalize the Open Offer. Resp. Post-Tr. Br. at 153, 173. Thus, Illumina's post-Acquisition incentives will be critical in steering how Illumina ultimately interprets and implements the Open Offer's incomplete terms. As Respondents' own expert, Dr. Willig, has explained, "if the

<sup>&</sup>lt;sup>118</sup> In fact, Illumina has already disengaged from these negotiations. (CCFF ¶¶ 4396-97, 4451).

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." (CCFF  $\P$  4192). For these reasons, no matter the robustness of the Open Offer's terms, MCED test developers recognize that Illumina's post-Acquisition incentives will compel Illumina, as a rational profit-maximizing business, to find ways to favor Grail over its rivals to the detriment of competition. *See, e.g.*, (CCFF  $\P$  2830) {

(CCFF ¶ 2836) (Helio's former CEO testifying that he could envision "a million different ways" that Helio and Illumina could have collaborated, but post-Acquisition will "have to be more guarded").

Even if the Open Offer is flawed, however, Respondents argue that Illumina remains incentivized to "expand access to NGS for all of its customers." Resp. Post-Tr. Br. at 174. As discussed extensively in Complaint Counsel's post-trial brief, *see* CC Post-Tr. Br. § II.E.1.b, the Acquisition alters Illumina's incentives substantially from that of a disinterested platform provider to that of an aggressive competitor in the MCED test market. 119

<sup>&</sup>lt;sup>119</sup> Rather than address the clear financial incentive to favor Grail, Respondents erroneously liken Illumina's post-Acquisition incentives to those 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. Unlike in *Fruehauf*, Illumina does not risk its customers "retaliating by shifting to competing suppliers" as there are no alternatives to Illumina for NGS tests. Accordingly, here, it makes

#### 4. Illumina Can Easily and Surreptitiously Evade the Provisions of the Open Offer

Respondents argue that various intrinsic and extrinsic reasons prevent Illumina from evading its commitments under the Open Offer. Complaint Counsel has already addressed *supra* and in its post-trial brief the flaws of the audit and arbitration provisions of the Open Offer, but a few remaining arguments must be addressed. First, Respondents argue that customers can "evaluate costs and benefits and undertake arbitration in circumstances where it is cost-effective." Resp. Post-Tr. Br. at 177. Once again, Respondents are confusing a bargained-for, ordinary course contract with a remedy to an anticompetitive merger. The latter is not effective only if a harmed customer has the resources to enforce it and the nerve to challenge its sole source supplier. See (CCFF ¶ 4942) (FMI's Fiedler testifying that engaging in a contractual dispute with Illumina "would be of very grave concern"); (CCFF ¶ 4932) {

(CCFF ¶ 4941) (Guardant's Getty testifying that "poking the bear is not exactly a good idea"). Further, requiring customers to use their resources to enforce Illumina's contractual commitments raises MCED test developers' costs relative to Grail, who would not need to expend resources in contractual disputes against Illumina. *See* (CCFF ¶ 4946). Moreover, forcing customers to engage in arbitration "ties up [the customers'] time and energy and resources that could be deployed" towards increased innovation. (CCFF ¶¶ 4938-39). Rather than put the onus on the customers, any "risk should be borne by the parties,

<sup>&</sup>quot;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.

Respondents also claim that if Illumina attempts to revoke the Open Offer, "customers could also sue Illumina under the promissory estoppel doctrine." Resp. Post-Tr. Br. at 175-76. This again puts the onus on customers to spend time and money to battle their sole supplier *after* Illumina causes them harm.

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who seek to consummate a merger that would otherwise violate Section 7." DOJ Merger Remedies Manual § II.

Second, Respondents disingenuously claim that Illumina's reputation could somehow be harmed by breaching the Open Offer, noting that "[g]iven the public scrutiny of the Open Offer, if Illumina failed to follow through on its commitments, it would face tremendous backlash from its customers" and there would be "reputational costs" associated with doing so. Resp. Post-Tr. Br. at 177-78. Respondents ignore, though, that Illumina specifically crafted the Open Offer so that any potential breach by Illumina would remain confidential through a confidential and binding arbitration process. (CCFF ¶ 4934). Rather than face "tremendous backlash from its customers," the Open Offer ensures that no one will be made aware of Illumina's breaches, except for Illumina and its aggrieved customer. 121 Moreover, as discussed in greater detail *supra*, even if a breach were discovered, it is difficult to imagine how it would worsen Illumina's already dismal reputation among its customers. See, supra, § III.C.2. Illumina has long had a reputation for disparaging and damaging its "enemies" that threaten its business in any way, including its own customers that cross over to competitors. See, e.g., (CCFF ¶ 3080) (Flatley writing in an internal document, "May God have mercy on my enemies, because I will not!"); (CCFF ¶ 3491)

And Illumina is not shy about using its position to the detriment of its customers. {

Respondents once again improperly cite to Complaint Counsel's expert, Dr. Fiona Scott Morton, claiming she acknowledged that "compliance with the Open Offer will have a favorable impact on Illumina's reputation." *See* Resp. Post-Tr. Br. at 178 (citing RPFF ¶ 998.5). Instead, when asked this question by Respondent counsel, Dr. Scott Morton repeatedly answered that she

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D. The Proposed Consent Decree Fails To Restore Competition
Despite the Open Offer's extensive deficiencies, Respondents argue that {
} will suddenly resolve all anticompetitive
<u> </u>
concerns. Resp. Post-Tr. Br. at 178. But simply memorializing an inadequate proposal in the form
of a Commission Order and forcing it onto customers who neither negotiated nor agreed to its
terms, will not remedy the anticompetitive effects of the Acquisition. As the evidence shows, the
Open Offer is far from the pinnacle of customer contracts; customers could and did achieve
superior contractual terms outside of the unilateral agreement. See, e.g., {
}; see also Resp. Post-Tr. Br. at
162 (noting that some "customers may still prefer their pre-merger pricing"). And different
customers may have different priorities and different business needs, which cannot be reflected in
a one-size-fits-all agreement. If Respondents' proposed remedy was ordered, though, Illumina
would have no incentive to offer anything to its oncology customers than this standardized
agreement for the next 12 years. It is for these reasons, and more, that a remedy to an unlawful

merger must not be a unilateral set of terms drafted by the merging parties and imposed onto the Government, customers, and ultimately American consumers.

Moreover, a consent decree involving such a complex behavioral remedy that raises tricky monitoring and enforcement issues would require substantial government oversight and regulation. Excessive government entanglement in such an innovative industry would subvert a thriving free market, 122 which courts and agencies strongly disfavor. *See St. Alphonsus*, 778 F.3d at 793 (9th Cir. 2015) ("[C]onduct remedies risk excessive government entanglement in the market."); *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 988 F.3d 690, 720 (4th Cir. 2021); DOJ Merger Remedies Manual § II (noting that remedies should not create ongoing government regulation of the market; "[c]onduct remedies substitute central decision making for the free market"). And the costs of this regulation will fall on American taxpayers.

While Respondents proceed to list behavioral remedies that the Commission has accepted in the past, *see* Resp. Post-Tr. Br. at 179, 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;

<sup>&</sup>lt;sup>122</sup> As the DOJ's former Assistant Attorney General Makan Delrahim said in a speech, "at times antitrust enforcers have experimented with allowing illegal mergers to proceed subject to certain behavioral commitments. That approach is fundamentally regulatory, imposing ongoing government oversight on what should preferably be a free market." U.S. Dep't of Justice, Antitrust Div., Assistant Attorney General Makan Delrahim Delivers Keynote Address at American Bar Association's Antitrust Fall Forum, (Nov. 16, 2017). He added that "[i]nstead of protecting the competition that might be lost in an unlawful merger, a behavioral remedy supplants competition with regulation; it replaces disaggregated decision making with central planning.").

it is whether the Respondents' Open Offer fully restores the competitive status quo that existed prior to the merger. For all the reasons already stated, it does not.

Respondents further argue that "[c]onsent 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." Resp. Post-Tr. Br. at 179. Respondents' contention that they are willing to be bound by the terms contained in an order is neither unique nor 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. Divestiture will achieve this goal; the Open Offer will not. 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.

### V. Respondents' Alleged Efficiencies Do Not Offset the Harm to Competition

Respondents claim that the Acquisition "will result in numerous, merger-specific benefits [including] sav[ing] many thousands of lives (in the U.S. and throughout the world) and billions of dollars," and that these benefits "easily outweigh the alleged harm." Resp. Post-Tr. Br. at 181. However, Respondents have failed to substantiate their 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).

First, Respondents argue that numerous courts have found efficiencies to justify otherwise anticompetitive mergers. *See, e.g.*, Resp. Post-Tr. Br. at 189, 199, 206-07. However, as both this Court and numerous Circuit Courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. <sup>123</sup> *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*, 778 F.3d at 790. 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. <sup>124</sup>

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<sup>123</sup> 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).

<sup>&</sup>lt;sup>124</sup> See, e.g., 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."); 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. Great Lakes Chem. Corp., 528 F. Supp.

Second, Respondents assert that each of their efficiency claims "was supported by every Illumina and Grail witness to testify about them." Resp. Post-Tr. Br. at 181. However, even just a cursory examination of the cited support for Respondents' claims shows that Respondents have failed to satisfy their burden of demonstrating that 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 FTC v. Hackensack Meridian Health, Inc.*, 2022 WL 840463 (3d Cir. Mar. 22, 2022), at \*10-11; *Heinz*, 246 F.3d at 720; *Staples*, 190 F. Supp. 3d at 137 n.15; *Sysco*, 113 F. Supp. at 82. To satisfy the "verifiability" prong, Respondents must 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

<sup>84, 87 (</sup>N.D. III. 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)); 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. 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"); see also 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.").

benefits of the Acquisition.<sup>125</sup> 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." 833 F. Supp. 2d at 91.

Additionally, Respondents have conducted no integration planning and as such have not and indeed cannot provide sufficient details describing the timing, scope, and likelihood of achieving any of the efficiency opportunities. In *Otto Bock*, this Court held that the respondent had "failed to demonstrate that the integration team sufficiently verified the synergies estimates in its financial model, or that the estimates are non-speculative" where "the evidence shows that Ottobock had not yet made decisions regarding integration plans . . . which could affect the identified synergy opportunities in these areas." 2019 WL 2118886. at \*52 (Chappell, A.L.J.). Similarly, here multiple Illumina and Grail executives confirmed at trial that, despite Illumina consummating the Acquisition in August 2021, no such integration planning has occurred. \*See (CCFF ¶¶ 5095-5126, 5433-43).

(CCFF ¶¶ 5433-34). Grail's Chief Medical Officer, Josh Ofman, explained that he had

<sup>125</sup> Respondents repeatedly assert that "Complaint Counsel either conducted no cross examination of these witnesses on the [Acquisition's] benefits or its questioning readily affirmed the efficiencies." Resp. Post-Tr. Br. at 181-82. As discussed below, Complaint Counsel's robust cross-examinations of Respondents' witnesses, coupled with other testimony and ordinary course documents, demonstrates that Respondents failed to quantify the magnitude of their efficiencies as well as the likelihood that they would be achieved. *See infra* CC Post-Tr. Reply Br. § V.A-G; *see also* CC Post-Tr. Br. at 154-172; (CCFF ¶¶ 5014-5966).

<sup>&</sup>lt;sup>126</sup> For example, Grail's CEO, Hans Bishop, and Grail's point-person for integration, Aaron Frieden, both testified at trial that integration planning between Illumina and Grail has not started, (CCFF ¶ 5095), and that besides financial reporting, no other integration has taken place since the close of the Acquisition. (CCFF ¶ 5099). Illumina's CEO similarly testified that Illumina's and Grail's {

The post-trial history of the AT&T/Time Warner merger—a case Respondents repeatedly tout throughout their brief—highlight why vague pronouncements from business executives on purported benefits from a vertical transaction are insufficient to meet Respondents' burden to show cognizable efficiencies. In AT&T, the parties' business executives and economic expert, Dr. Carlton (the same expert retained by Respondents here), opined that AT&T's acquisition of Time Warner would result in significant efficiencies. But just four years after AT&T acquired Time Warner, it unwound the merger at a substantial loss. (PX7134 (Carlton Dep. at 42-43)). During his deposition in this matter, Dr. Carlton conceded that "AT&T did not achieve what it hoped to achieve" and "that the parties thought [it] would produce an efficiency, though it ultimately didn't." (PX7134 (Carlton Dep. at 43, 57)); see also (PX0398) at 022 ("Michael Katz on Challenges to Antitrust Policy")) ("But I think what's turned out to be the case with [the AT&T/Time Warner merger] is that the vertical synergies that the parties claimed turned out not to be as big as they thought."). In fact, instead of producing benefits, the merger quickly harmed consumers: "Within months of completing the deal, AT&T withheld HBO from Dish during contract negotiations, thereby fulfilling opponents' predictions about how the merged entity would use its power to exercise leverage. And while AT&T had stated that the transaction would enable it to lower consumer prices, AT&T has increased prices instead, raising some bills by fifty percent." Lina M. Khan, The End of Antitrust History Revisited, 133 Harv. L. Rev. 1655, 1673-74 (2020) (reviewing Tim Wu, The Curse of Bigness: Antitrust in the New Gilded Age (2018)). AT&T thus reinforces why courts have required "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); CCC Holdings, Inc., 605 F. Supp. 2d at 72-73.

### A. Respondents' "Lives Saved" Efficiency Is Not Cognizable

Respondents' primary efficiency claim is that the Acquisition will accelerate the adoption of Grail's Galleri MCED test, and in turn, this acceleration will save lives. Resp. Post-Tr. Br. at 182. 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." CC Post-Tr. Br. 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. 127

First, Respondents claim that the Acquisition will save lives is supported only by estimates performed by their economic expert, Dr. Carlton. Resp. Post-Tr. Br. at 185. Specifically, Dr. Carlton estimated that a one-year acceleration of Galleri would result in "7,429 to 10,441" lives saved. *Id.* However, Dr. Carlton admitted that he did not opine whether Illumina *could* accelerate FDA or payer approval—he simply relied upon on Illumina's own claims that it could achieve such acceleration. (CCFF ¶¶ 5075, 5077, 5432). {

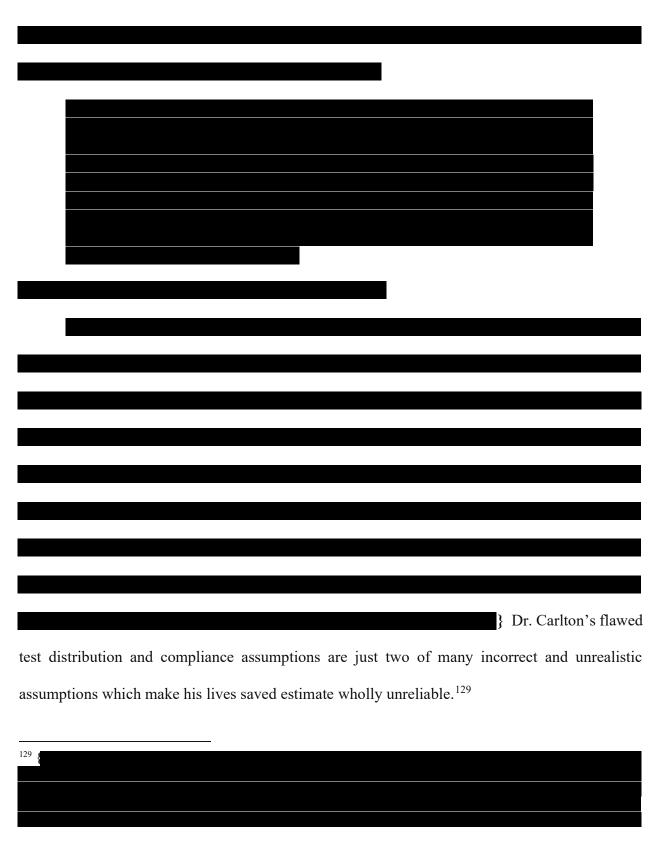
} (CCFF ¶¶

5079-80). As discussed infra §V.B, Respondents have failed to show that the Acquisition will

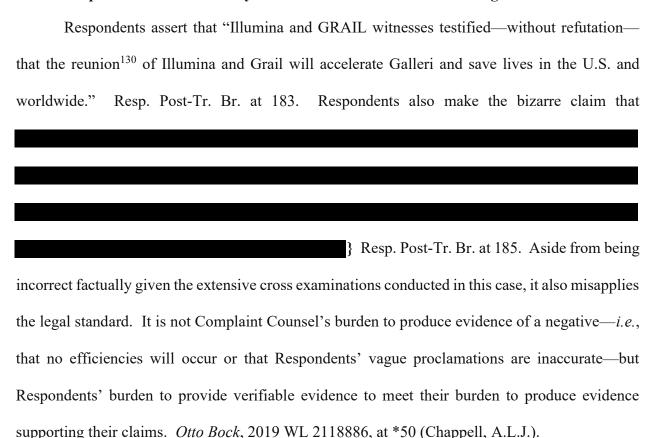
<sup>&</sup>lt;sup>127</sup> As discussed extensively in Complaint Counsel's Post-Trial Brief, the loss of innovation and commercial MCED competition as a result of the Acquisition will cost lives. *See* CC Post-Tr. Br. at 133-144; *see also* (CCFF ¶¶ 3570-3668).

accelerate adoption of Galleri (or that such acceleration would be merger specific), and thus, Dr. Carlton's estimate is irrelevant.

Even assuming arguendo that Respondents had demonstrated that the Acquisition would
accelerate the adoption of Galleri by some amount of time, the methodology used by Dr. Carlton
to estimate life-years saved or lives saved is not verifiable and is based on flawed assumptions. 128
}
Dr. Carlton's estimate in terms of lives saved suffers from similar methodological
deficiencies which preclude verification. For example, {
128 (CCFF <sup>9</sup>
5369).



#### B. Respondents' FDA and Payer Acceleration Claims Are Not Cognizable



}

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.*, Resp. Post-Tr. Br. § IV. 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* CC Post-Tr. Br. § 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.

As this Court explained in *Otto Bock*, 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.). As discussed below, 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, the weight of the record evidence—including admissions by Respondents' executives under cross-examination—actually shows that Illumina is *unlikely* to achieve any acceleration of Galleri's FDA approval or payer acceptance. Further, Respondents admitted they have not estimated the costs necessary to achieve the alleged acceleration, as they have not even begun the integration *planning* related to these activities. Accordingly, Respondents' acceleration claims are not cognizable.

#### 1. Respondents' Acceleration Claims Are Not Verifiable

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 vague speculation from Respondents' executives and experts regarding the possibility of FDA or payer

acceleration falls well short of satisfying this standard and is contradicted by the weight of the evidence which shows Illumina lacks the resources, expertise, and plans to actually achieve any such acceleration. As Illumina's former Chief Medical Officer recognized when forming Grail, "Illumina has no IP, no special data or expertise or idea to put into [Grail]." (CCFF ¶ 5028).

#### a. Respondents Do Not Estimate the Magnitude of Any Alleged Acceleration

Respondents concede that they have not estimated the magnitude of the acceleration (*i.e.*, how much more quickly they believe Illumina could accelerate FDA or payer approval). In their post-trial brief, Respondents acknowledge "it is difficult to quantify with precision the extent to which the Acquisition will accelerate the wide-spread adoption of Galleri," providing only their executives' unsubstantiated "belief" Illumina would accelerate "Galleri's adoption by at least one year." Resp. Post-Tr. Br. at 185. Indeed, at trial, Grail's CFO admitted that when Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (CCFF ¶ 5069). <sup>131</sup>

Additionally, widespread adoption of Galleri requires the successful completion of two distinct requirements: (1) FDA approval of a PMA (which involves submission of a lengthy application involving clinical and analytical validation data collected during clinical trials using the device) (CCFF ¶ 5032); and (2) coverage and reimbursement for Galleri by public payers such as CMS and private insurers. (CCFF ¶¶ 5409-10). These two tasks involve different regulatory requirements, government agencies, third-parties, and internal teams within Illumina and Grail.

<sup>131</sup> Grail's CFO also testified that neither Grail's Financial Projections and Analysis ("FP&A") team nor Medical Affairs and Regulatory teams conducted an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (CCFF ¶¶ 5070-5071). Similarly, Illumina's Chief Medical Officer testified at trial that Illumina {

(CCFF ¶¶ 5029-32, 5259-5363, 5415-19, 5483-89, 5491-5587). Yet nowhere do Respondents identify *how much* of the acceleration is attributable to quicker FDA approval versus payer acceptance. For example, Grail's CEO at the time of the Acquisition 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). Having not even identified how much the alleged acceleration is attributable to FDA processes versus payer processes, it is impossible to test and verify this claim by reasonable means.

# b. Respondents' Cited Evidence Does Not Substantiate the Likelihood or Magnitude of the FDA Acceleration

Rather than producing an analysis detailing how Illumina would specifically accelerate payer approval (including the assumptions for the acceleration and the magnitude), Respondents instead rely on vague characterizations about the comparative abilities of Illumina versus Grail in support of their acceleration claims. *See* Resp. Post-Tr. Br. at 191-92. For example, Respondents highlight testimony from *Grail*'s former CEO, Hans Bishop that "

Resp. Post-Tr. Br. at 184 (quoting RPFF ¶ 1121.6) (emphasis added). Examination of the testimony of Respondents' executives—including their admissions on cross-examinations—reveals that they lacked foundation for their vague assertions and were unable to substantiate Respondents' assurances and beliefs of their FDA and

For example, Respondents extensively cite

See Resp. Post-Tr.

Br. at 184, 191-192, 194.

were mere unsupported speculation not based

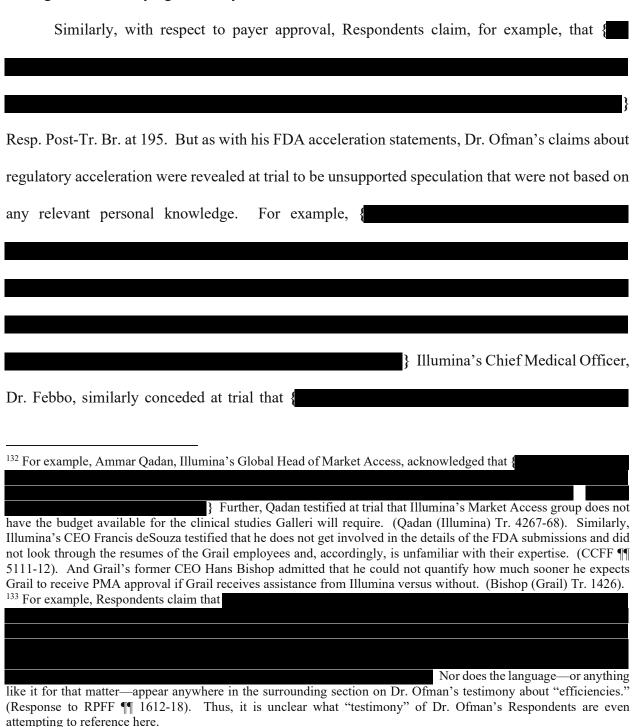
payer claims.

on any relevant personal knowledge. Conceded on cross examination that {
}
Moreover, Dr. Ofman has {
Pr. Ofman demonstrated at trial that h
was unaware of even the most basic information about Illumina's regulatory experience. H
conceded on cross examination that he: (1) did not know how many PMA approvals Illumina ha
obtained or whether that number was greater than one; (2) did not know whether the FDA approve
Illumina received for its sequencer was a PMA approval or not; (3) did not know the name of the
only IVD test for which Illumina had received PMA approval; (4) did not know the date on which

that approval was granted, or whether the approval had taken place within the last four years; (5) was not familiar with the specific details of Illumina's interactions with the FDA relating to its approved IVD test; (6) did not know how long Illumina has been attempting to secure PMA approval for its TSO-500 therapy selection test; (7) did not know how successful or unsuccessful Illumina's efforts towards achieving approval for its TSO-500 therapy selection test have been; and (8) 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 acceleration claims. See Resp. Post-Tr. Br. at 193-95. But like Dr. Ofman, cross-examination of Dr. Febbo revealed that his views on the ability of Illumina to accelerate FDA approval was merely vague speculation lacking personal knowledge. For example, { } (CCFF ¶ 5083). { } (CCFF ¶¶ 5091-92). Dr. Febbo also admitted that { } And he conceded that he { The other business executives cited by Respondents similarly failed to

substantiate that their views on acceleration were more than mere unfounded speculation. And some of the statements Respondents attributed to their executives do not even appear in the cited findings or the underlying testimony. 133





Finally, Respondents' cited experts do not offer substantiation for the likelihood or magnitude of their acceleration claims. For example, Respondents' economic expert, Dr. Carlton, admitted that he was not opining that Illumina could accelerate FDA or payer approval—he was merely relying on Illumina's claims that it could achieve such acceleration. (CCFF ¶ 5075, 5077, 5432). Similarly, Respondents rely on the testimony from Dr. Deverka that "the reunion of Illumina and GRAIL will accelerate GRAIL's FDA approval, CMS coverage and payor coverage," including a chart compiled from her expert report purporting to compare the capabilities of Illumina versus Grail. Resp. Post-Tr. Br. at 196-97. But notably, Dr. Deverka admitted at trial that she \$

} In fact, Dr.

Deverka conceded during her trial testimony that she could not quantify the probability that Illumina could accelerate the market access of Grail's Galleri. (RX6001 (Deverka Trial Dep. at 132-33)). Thus, it is unsurprising that Respondents' ordinary course documents, made prior to this litigation, admit that "[w]e do not expect material synergies to the transaction." (CCFF ¶ 5040).

<sup>134</sup> Another Illumina document similarly noted that {
(CCFF ¶ 215). And, {
(CCFF ¶ 5124).

## c. The Weight of the Record Evidence Shows that FDA Acceleration Is Unlikely To Occur

Although Respondents' failure to satisfy its burden of substantiating its efficiency claims is sufficient for the Court to conclude that Respondents do not have a valid efficiencies defense, see Otto Bock, 2019 WL 2118886, at \*50 (Chappell, A.L.J.), Complaint Counsel also has produced robust record evidence showing that Illumina is in fact unlikely to accelerate the FDA approval or payer acceptance of Galleri. Contrary to Respondents' assertions that Illumina has superior experience and resources than Grail with respect to regulatory approval and market access, Resp. Post-Tr. Br. at 191, the evidence demonstrates that Illumina lacks the necessary expertise and capabilities.

For example, {			
			}

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. <sup>135</sup> To date, Illumina

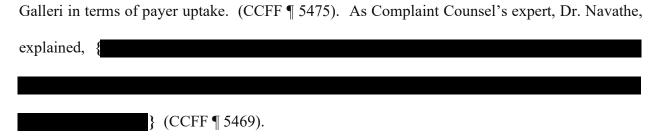
<sup>&</sup>lt;sup>135</sup> As noted *supra*, Illumina initially chose to spin Grail off as a separate company, rather than continue Grail's development internally. In spinning Grail off, one benefit Illumina recognized was that a new company could "retain[]

has only received one PMA approval from the FDA { which is the type of FDA approval that would be required for Grail's Galleri test. (CCFF ¶ 5146). 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). Given 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, it is speculative what benefit—if any—Illumina's limited experience working with payers in other settings will provide in its attempt to accelerate payer approval of Galleri. *See* (CCFF ¶¶ 5466-78). Notably, Illumina only employs thirteen employees responsible for payer relationships, and only two of these employees focus on payer relationships in the United States. (Qadan (Illumina) Tr. 4289, 4292). And Illumina has completed only one risk-sharing agreement which was designed not by Illumina but rather by the University of Colorado. (CCFF ¶ 5472); (Qadan (Illumina) at Tr. 4271). This risk sharing agreement was related to NIPT, (CCFF ¶ 5473), which, according to Grail's VP of Market Access Qadan is not a good comparison for

and attract[] best-in-class people through equity, culture, and quality of the science." (CCFF  $\P$  24). In fact, Illumina stated in internal Q&A bullets that it "believe[d]" that divesting Grail would "accelerate the liquid biopsy market for all." (CCFF  $\P$  5843).

<sup>136</sup> Illumina's other {



Consistent with this record evidence, Illumina's lack of clinical and regulatory expertise was highlighted by multiple financial analysts shortly after the Acquisition was announced. For example, a JP Morgan analyst observed that Illumina's acquisition of Grail:

represents a far stretch from [Illumina]'s core expertise, as early cancer detection through liquid biopsy requires significant market development involving lengthy large-scale clinical trials and regulatory approvals, clinical guidelines and reimbursement, as well as commercial infrastructure investment from scratch, none of which have much to leverage from [Illumina]'s core business today.

(CCFF ¶ 5460); see also (CCFF ¶ 5461) (Cowen Analyst Report stating that "[W]e don't see the clear fit for acquiring a company that . . . is still at a stage where clinical studies and clinical product development are still critical and will be for years, and . . . would benefit from true clinical commercial infrastructure/reach that does not really exist at Illumina, and . . . arguably would benefit most from accessing new technologies that do not currently reside at Illumina.").

In contrast to Illumina, Grail is already pursuing FDA acceleration independently, see (CCFF ¶¶ 5259-5363), having created a well-established regulatory team, see (CCFF ¶¶ 5291-95). Grail's regulatory team, in its own words, possesses {

}
In
addition, Grail describes its clinical study program as "one of the largest clinical study programs
ever conducted in genomic medicine," (CCFF $\P$ 5299), and has told investors that it has "invested
significant capital and resources in [its] foundational studies, which have collectively enrolled
approximately 115,000 participants, to build what we believe are the largest linked datasets of
genomic and clinical data in the cancer field." (CCFF $\P$ 5300). In total, Grail has directly enrolled
over 130,000 participants in clinical studies, which is more than ten times the number of patients
that Illumina has directly enrolled in clinicals studies. (CCFF $\P\P$ 5302, 5309); see also (CCFF $\P$
5310) (largest number of participants that Illumina has directly enrolled in a clinical study is only
three thousand participants). {
} (CCFF ¶ 5349).
With respect to payer approval, Grail already is marketing Galleri to health systems,

With respect to payer approval, Grail already is marketing Galleri to health systems, concierge physicians, self-insured employers, and life science companies and has brought in a

highly skilled group of professionals to help achieve Grail's reimbursement strategy. *See* (CCFF ¶ 5479-5630). Hans Bishop, Grail's former CEO, testified at trial that Grail has "built all of the infrastructure, laboratory infrastructure, necessary to reliably deliver [Galleri] in full compliance with all of the regulatory requirements of running such a test in a lab." (CCFF ¶ 5488). In fact, Respondents' own expert, Dr. Patricia Deverka, testified that she believes Grail can obtain reimbursement and coverage for Galleri on its own. (CCFF ¶ 5479). Thus, evidence indicates that independently Grail is on track—in fact ahead of schedule—to receive FDA approval and payer reimbursement for Galleri.

In light of these facts, it is unsurprising that Illumina's ordinary course deal documents reflect far less confidence in Illumina's ability to achieve any efficiencies than their executives vague trial testimony. For example, in a September 2020 Illumina FAQ document relating to Illumina's acquisition of Grail, an "Employee FAQ" section stated: "We do not expect material synergies to the transaction." (CCFF ¶ 5040). Illumina's claimed FDA acceleration efficiency also is not reflected in the base case of Illumina's financial model that it used to value its acquisition of Grail. (CCFF ¶ 5043). Complaint Counsel's rebuttal expert, Dr. Rothman,

<sup>&</sup>lt;sup>137</sup> 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 {

<sup>{ (</sup>Freidin (Grail) Tr. 3076 (*in camera*)); (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. *See* (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 Q3 2021 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

explained that	{			
		} (	CCFF ¶ 5057).	

## d. Acceleration Efficiencies Are Too Preliminary To Be Cognizable

As noted *supra*, Respondents have yet to hold any integration meetings to plan and define where Illumina could accelerate Grail's objectives—including planned meetings between clinical affairs, regulatory affairs, commercial, and lab teams. (CCFF ¶ 5100, 5102-06). According to Phil Febbo, Illumina's Chief Medical Officer, Illumina will not be able to "work together [with Grail] and find those specific areas where [Illumina] can help [Grail] accelerate" until Illumina and Grail are combined. (CCFF ¶ 5116). For example, with respect to the FDA acceleration claims, Febbo conceded that {

(CCFF ¶¶ 5084-88). Grail's former CEO likewise testified at trial that he could not answer how many employees Illumina plans on deploying to assist with the PMA "because to answer such a question, integration planning would have to be under way . . . and integration planning hasn't started." (CCFF ¶ 5097); see also (CCFF ¶ 5107). Dr. Ofman, Grail's Chief Medical Officer, similarly explained at trial that {

(Ofman (Grail) Tr. 3380)

(in camera)). Similarly, with respect to payer acceleration, Dr. Febbo admitted at trial that

(CCFF ¶ 5437). Given the absence of any meaningful integration planning regarding the alleged acceleration efficiencies, Respondents have "failed to demonstrate that the integration team sufficiently verified the synergies estimates in its financial model, or that the estimates are non-speculative." *Otto Bock*, 2019 WL 2118886, at \*52 (Chappell, A.L.J.) (holding that respondent failed to substantiate efficacies where "the evidence shows that Ottobock had not yet made decisions regarding integration plans . . . which could affect the identified synergy opportunities in these areas.").

#### 2. Respondents' Acceleration Claims Are Not Merger Specific

"A merger-specific efficiency is one that 'cannot be achieved by either company alone because, if they can, the merger's asserted benefits can be achieved without the concomitant loss of a competitor." *Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.) (quoting *Heinz*, 246 F.3d at 721-22); *see also Hackensack*, 2022 WL 840463, at \*11. Respondents argue that the acceleration efficiencies are mergers specific because "Illumina's capabilities with regulatory approval, market access and international expansion are a product of years of work and cannot be easily replicated" and because Grail "could not achieve these efficiencies by hiring additional personnel or outside consultants." Resp. Post-Tr. Br. at 224. However, 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. 138 *See supra* § V.B.1.b-d.

<sup>&</sup>lt;sup>138</sup> 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. *See infra* § V.C.2.

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 Acquisition. 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, { { (CCFF ¶ 5385). Respondents' own expert, Dr. Deverka, conceded during her trial deposition that { RX6001 (Deverka Trial Dep. at 148) (in camera)), and Grail's Additionally, as Aaron Friedin, Grail's Chief Financial Officer, testified, { } (CCFF ¶ 5388). { } (CCFF ¶¶ 5394-95). { } (CCFF ¶ 5392).

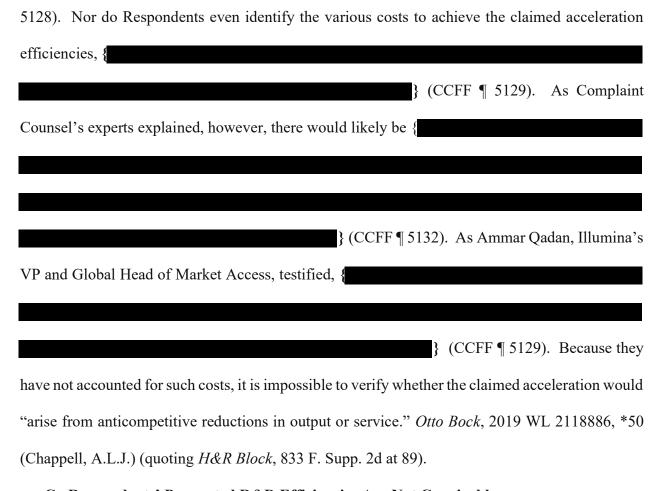
Further, other companies in the industry possess more experience than Illumina marshalling products through the FDA's PMA process, and thus, could provide alternatives to the Acquisition. Numerous companies, including Abbott, Becton Dickinson, Biogenex Laboratories, Bio-Merieux, Epigenomics AG, Exact, FMI, Gen-Probe Inc., Guardant Health, Hologic, Invivoscribe, Myriad, Roche, Siemens, and Thermo Fisher, among others, have received PMA approval for IVD tests. (CCFF ¶ 5408). 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, FMI, 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. 3447-48).

#### 3. Respondents Have Not Substantiated the Costs of the Acceleration Claim

Respondents' acceleration efficiencies are not cognizable because Respondents have not estimated the costs associated with achieving FDA or payer acceleration. *See Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.) (explaining the merging firm must substantiate "how and when each would be achieved (and any costs of doing so)"). In its Responses & Objections to FTC Requests for Admissions, {

} (CCFF ¶

<sup>139</sup> Respondents cite Illumina's quality management system as one reason why they believe Illumina is uniquely positioned to assist with acceleration. But Grail's Chief Medical Officer, 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).



### C. Respondents' Purported R&D Efficiencies Are Not Cognizable

Respondents next claim that "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." Resp. Post-Tr. Br. at 200. Essentially, Respondents argue that "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 and for which its technology may be able to unlock substantial discoveries that improve human health" whereas "Illumina is a larger company with the financial resources to focus on

R&D." Resp. Post-Tr. Br. at 200. Respondents fail to demonstrate that these R&D claims are either verifiable, merger-specific, or would be passed through to consumer to their benefit.

## 1. Respondents' Claimed R&D Efficiencies Are Not Verifiable

To substantiate an efficiency claim, this Court has held that Respondents must 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. This requires the respondent to present evidence representing "more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721; *see also Wilh. Wilhelmsen*, 341 F. Supp. 3d. at 72; *CCC Holdings, Inc.*, 605 F. Supp. 2d at 72-73. The evidence cited by Respondents in support of their R&D claims, however, consists merely of vague, conclusory opinions by Respondents' executives about potential R&D efforts post-Acquisition. For example:

- Respondents cite Illumina executive Dr. Febbo for his vague assertion that Illumina could improve the Galleri test in unspecified ways using an unquantified amount of additional data.<sup>140</sup>
- Respondents highlight Illumina executive Dr. Aravanis's opinion that the merger could lead to unspecified "novel" discoveries in the broad areas of "fatty liver disease or neurodegenerative disease." <sup>141</sup>

<sup>&</sup>lt;sup>140</sup> See, e.g., Resp. Post-Tr. Br. at 202 (citing (RPFF ¶ 1141.3) ("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.")).

<sup>&</sup>lt;sup>141</sup> See, e.g., Resp. Post-Tr. Br. at 203 (citing (RPFF ¶ 1142.2) ("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,

- Respondents highlight that Illumina's CEO Frances deSouza testified that post-Acquisition that combined firm would try "to identify the genomic biomarkers in blood for other conditions, like fatty liver disease, neurological conditions like Alzheimer's and Parkinson's."<sup>142</sup>
- Respondents cite Grail's former CEO Han Bishop's unremarkable testimony that Illumina is a "large, successful, profitable company" that "understand[s] the importance of ongoing investment in research and development." <sup>143</sup>

Mere identification of possible R&D projects, however, is different from demonstrating a cognizable efficiency that can be verified by reasonable means. For example, the claimed R&D efficiencies that Respondents contend 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. Indeed, 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

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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.")).

<sup>&</sup>lt;sup>142</sup> See, e.g., Resp. Post-Tr. Br. at 202 (citing (RPFF ¶ 1142.1) ("We believe that . . . 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.")).

<sup>&</sup>lt;sup>143</sup> See, e.g., Resp. Post-Tr. Br. at 202 (citing (RPFF ¶ 1141.5) ("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 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.")).

directing their efforts toward any R&D efficiencies. (CCFF ¶ 5730). Indeed, Respondents' 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). In fact, Illumina's CEO described

(PX7107 deSouza (Illumina) Dep. at 155.) As Complaint Counsel's efficiency expert correctly explained,

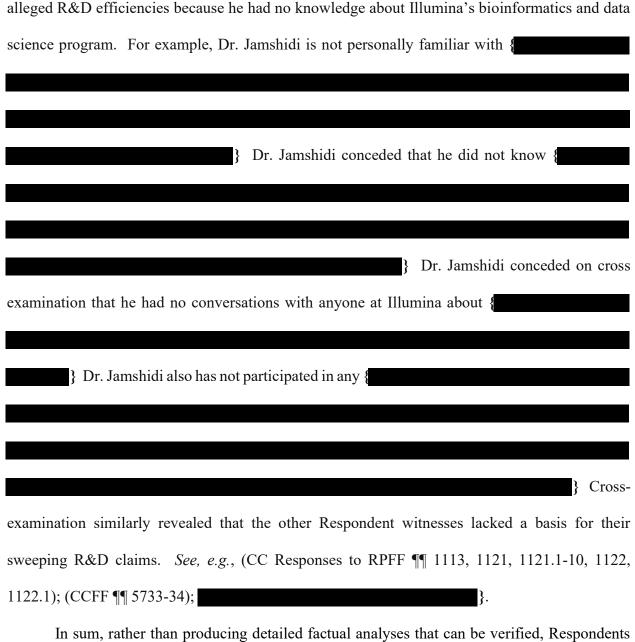
Second, Illumina's internal documents directly contradict its claims that the Verinata transaction was the source of the discovery leading to Galleri. Specifically, Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings

<sup>&</sup>lt;sup>144</sup> In an apparent attempt to bolster their executives' predictions that the Acquisition is likely to result in (unspecified) R&D break-throughs, Respondents make the bizarre suggestion that a prior Illumina transaction (the acquisition of Verinata in 2013) led to the "discovery that ultimately led Illumina to pursue development of an early cancer detection test and to found GRAIL." Resp. Post-Tr. Br. at 205. 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 Ahlquist, 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 Exact and Mayo Clinic entered into a research and development partnership in June 2009 that has continued for 12 years. (CCFF ¶ 360). 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).

Further, Respondents' witnesses lack a basis for their opinions regarding the potential to
achieve R&D efficiencies. For example, Respondents cite the testimony of Dr. Arash Jamshidi,
Grail's Senior Vice President of Data Sciences, that the Acquisition {
Resp. Post-Tr. Br. at 202 (quoting RPFF ¶ 1141.6). Respondents argue that Dr.
Jamshidi's testimony regarding this R&D efficiency "stands unrefuted" because "Complaint
Counsel did not even try to undermine this testimony through cross examination." Resp. Post-Tr.
Br at 202

Contrary to Respondents' assertion, robust record evidence—including cross-examination by Complaint Counsel—illustrates that Dr. Jamshidi had no basis for his speculation about such

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)).



In sum, rather than producing detailed factual analyses that can be verified, Respondents ask the court to simply rely on high-level predictions from its managers. As the court in H&R Block explained:

While 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. If this were not so, then the efficiencies

defense might well swallow the whole of Section 7 of the Clayton Act because management would be able to present large efficiencies based on its own judgment and the Court would be hard pressed to find otherwise. The difficulty in substantiating efficiency claims in a verifiable way is one reason why courts 'generally have found inadequate proof of efficiencies to sustain a rebuttal of the government's case.'

H&R Block, 833 F. Supp. 2d at 91 (quoting Heinz, 246 F.3d at 720 (citation omitted)); see also Staples, 970 F. Supp. at 1089 (finding "defendants failed to produce the necessary documentation for verification" of efficiencies). For the same reasons the courts in H&R Block and Staples rejected the unsupported efficiency claims, here, Respondents have similarly failed to produce evidence demonstrating the R&D efficiencies are verifiable.

### 2. Respondents' Claimed R&D Efficiencies Are Not Merger Specific

Respondents similarly fail to demonstrate that their vague R&D efficiencies are "a type of cost saving that could not be achieved without the merger." *Wilh. Wilhelmsen*, 341 F. Supp. 3d at 72. Respondents primarily claim that the alleged efficiency is merger-specific because Illumina has "expertise," "is a larger company with the financial resources," and "it would take GRAIL years to develop the R&D capabilities Illumina has today." Resp. Post-Tr. Br. at 200, 226-27. Respondents' vague assertions are insufficient to demonstrate merger-specificity as a matter of law, *see Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.), and additionally, are contradicted by the weight of the evidence.

<sup>&</sup>lt;sup>145</sup> Respondents also argue that the alleged R&D efficiencies are mergers-specific because "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," citing the opinion of their economic expert. Resp. Post-Tr. Br. at 227. Setting aside the factual inaccuracies, assessing whether Grail would have collaborated with Illumina or another third-party on these 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. *See Hackensack*, 2022 WL 840463, at \*11 (finding Respondents did not demonstrate merger-specificity where "the efficiencies cannot be achieved by either party alone").

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 Acquisition will lead to insights allowing Grail's technology to apply to other diseases, including "fatty liver disease," Resp. Post-Tr. Bt. 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 {

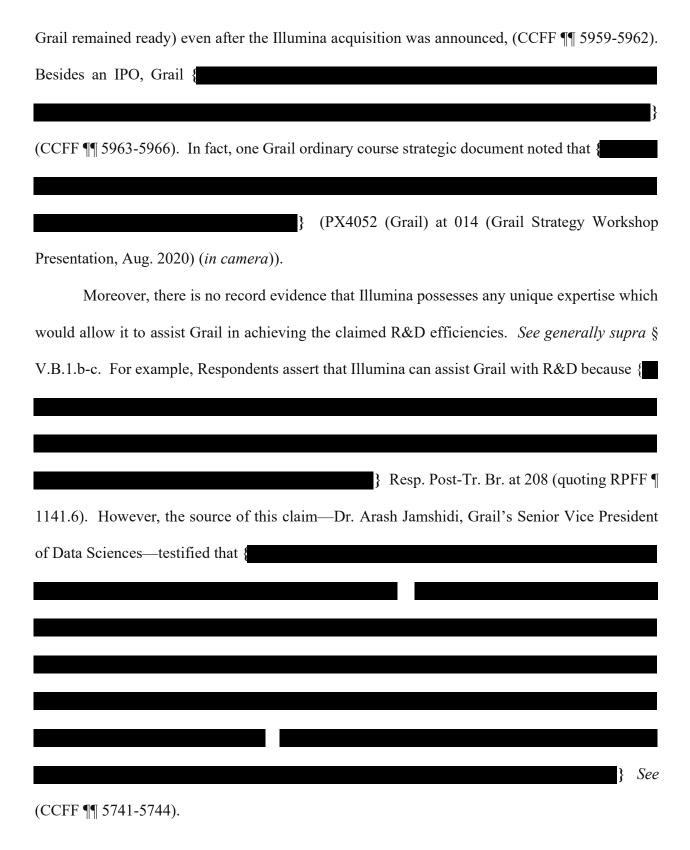
(CCFF ¶ 5747), as well as conducting {

(CCFF ¶ 5748-50). Thus, these alleged efficiencies are not merger specific because Grail could have achieved them as a standalone company. *See Hackensack*, 2022 WL 840463, at \*11 (finding Respondents did not demonstrate merger-specificity where "the efficiencies cannot be achieved by either party alone").

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, {

(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). {

(CCFF ¶¶ 5915-5952), and investors remained interested in a Grail IPO (and



# 3. Respondents Have Not Substantiated the Costs Associated With Claimed R&D Efficiencies or Shown They Would Be Passed Through To Benefit Customers

Respondents' R&D efficiencies claim also fails because Respondents have not identified the costs associated with achieving these efficiencies. It is undisputed that Respondents have not specified how much it would cost—either financially or in terms of human capital—for the efficiencies that Illumina claims the combined firm would pursue post-Acquisition. *See* (PX7134 (Carlton Dep. at 173)); *see also* (PX6092 (Rothman Rebuttal Report) ¶ 88 (*in camera*)). Instead, Respondents criticize Complaint Counsel's expert for pointing out the omission, arguing the Complaint Counsel's expert "does not explain why understanding the exact costs of these efficiencies is necessary in order for them to be cognizable." Resp. Post-Tr. Br. at 204. The reasons it is necessary to identify the costs of any efficiency is obvious—as Complaint Counsel's expert explained, {

(PX6092 (Rothman Rebuttal Report) ¶ 88 (*in camera*)). Stated differently, R&D efficiencies do not ultimately benefit consumers on net if they come at the cost of lost innovation in other areas. <sup>146</sup> For this reason, the law is clear that an efficiency cannot be credited if it "'arise[s] from anticompetitive reductions in output or service." *Otto Bock*, 2019 WL 2118886 (quoting *H&R* 

<sup>&</sup>lt;sup>146</sup> For example, Dr. Arash Jamshidi, Grail's Senior Vice President of Data Sciences, acknowledged that {

<sup>} (</sup>Jamshidi (Grail) Tr. 4069 (in camera)); (PX7107 (deSouza (Illumina) Dep. at 164)

Block, 833 F. Supp. 2d at 89); see also id. (explaining that the merging firm must substantiate "how and when each would be achieved (and any costs of doing so)").

Finally, many of the alleged R&D benefits appear related to diseases other than cancer. *See, e.g.*, Resp. Post-Tr. Br. at 203 (discussing fatty liver, cardiovascular, metabolic, inflammatory, and neurologic diseases). However, "[a]n anticompetitive merger cannot be justified on the basis of asserted efficiencies outside the relevant market." *Otto Bock*, 2019 WL 2118886, at \*49; *see also Phila. Nat'l Bank*, 374 U.S. at 370; *University Health*, 938 F.2d at 1222; *St. Alphonsus*, 778 F.3d at 790; *Heinz*, 246 F.3d at 715. Thus, many of the alleged R&D efficiencies are not cognizable because they do not relate to cancer and the relevant product market—MCED tests.

## D. Respondents' Alleged Royalty Reduction Is Not Cognizable

The fourth efficiency that Respondents alleged will result from the Acquisition is a reduction in the "royalties that GRAIL was required to pay Illumina before the Transaction." Resp. Post-Tr. Br. at 207. Respondents fail to satisfy their burden of demonstrating that the alleged royalty reduction is verifiable, mergers-specific, and will be passed on to consumers.

#### 1. Respondents' Royalty Claim Is Not Verifiable

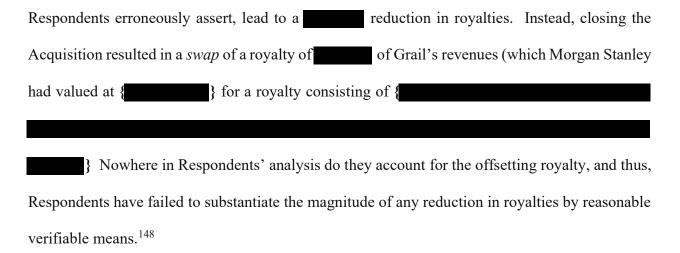
First, to substantiate the claimed royalty efficiency, Respondents must demonstrate that "it is possible to 'verify by reasonable means the likelihood and magnitude of [the] efficiency, how and when [it] would be achieved (and any costs of doing so), how [it] would enhance the merged firm's ability and incentive to compete, and why [it] 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). Respondents have failed to demonstrate the magnitude of the efficiency because they have not accounted for an offsetting royalty—Contingent Value Rights ("CVRs")—which issued simultaneously with the

closing of the transaction and offsets (if not entirely, at least in part) any reduction in the combined firm's margins. In essence, Respondents have swapped one royalty for another and claimed this as a cost savings.

While Respondents tout that the elimination of the groyalty payment from Grail to Illumina will reduce the combined firm's margins, Respondents ignore that the closing of the Acquisition created a new royalty payment—CVRs—which *increases* the combined firms' margins. (CCFF ¶ 5781). As consideration for the Acquisition, Grail shareholders could elect to receive consideration in CVRs. (PX0074 (Illumina) at 027-028 (Illumina Amended S-4)). The CVRs entitled the holders to a { (Freidin (Grail) Tr. 3076 (*in camera*)); (PX0074 (Illumina) at 217 (Illumina Amended S-4)). (Bishop (Grail) Tr. 1356). As Grail's Senior Vice President of Finance explained, these CVRs are also referred to as a { (Freidin (Grail) Tr. 3075 (*in camera*)), and Grail's CEO confirmed at trial that the CVR's impact the company's P&L just "like a royalty." (Bishop (Grail) Tr. 1357).

When Illumina consummated the Acquisition on August 18, 2021, "[h]olders of approximately 47% of GRAIL equity interests and/or awards (on a fully diluted basis), or 54% excluding Illumina, elected to receive the CVR consideration." (CCFF ¶ 5784). Illumina valued the CVR consideration owed to Grail's stockholders at \$762 million as of the acquisition's August 18, 2021 completion date. (CCFF ¶ 5783). Therefore, closing the Acquisition did not, as

<sup>&</sup>lt;sup>147</sup> { (CCFF ¶ 5770).



#### 2. Respondents' Royalty Claim Is Not Merger Specific

With respect to merger-specificity, the relevant question is not whether the merger eliminated the original royalty, but whether the elimination of the royalty is "a type of cost saving that could not be achieved without the merger." *Wilh. Wilhelmsen*, 341 F. Supp. 3d at 72. In an attempt to demonstrate merger-specificity for the claim, Respondents argue that the fact that the parties had not eliminated the royalty prior to the merger "is proof that there is no evidentiary basis to speculate that this efficiency would not be achievable by contract absent the merger." Resp. Post-Tr. Br. at 228. As demonstrated by record evidence, however, there are multiple reasons why Respondents may not have eliminated the royalty prior to their agreement to merge, and thus, the absence of its pre-Acquisition elimination is not "proof" of merger-specificity.

Prior to the Acquisition, Grail was in discussions with Morgan Stanley, its financial advisor, about seeking both a reduction in the royalty it paid to Illumina, as well as {

 $<sup>^{148}</sup>$  Additionally, Respondents' economic expert conceded that he failed to analyze the tax treatment of CVRs given to Grail shareholders compared to the tax treatment of original royalties that Grail paid to Illumina—a necessary analysis in order to properly estimate the magnitude of the efficiency. (CCFF ¶ 5785).

}. (CCFF ¶¶ 5763, { }). Grail, along
with Morgan Stanley, assessed different scenarios that could defer, eliminate, or decrease the
Illumina royalty, (CCFF $\P$ 5763), and they {
}. For example, Grail contemplated {
}. These are but two of many possible ways in which Grail could have eliminated the royalty
"without the merger." See Wilh. Wilhelmsen, 341 F. Supp. 3d at 72.
}. Grail's then-CEO never {
}, however, because 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
elimination of the royalty is merger specific.

Respondents' economic expert conceded that he did not specifically opine on whether the royalty that Grail paid to Illumina could have been eliminated absent the merger. (CCFF  $\P$  5777).

# 3. Respondents Have Not Shown the Royalty Reduction Will Be Passed to Customers

Finally, Respondents fail to produce "clear evidence" that this alleged efficiency "will offset the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.) (emphasis added) (quoting *Penn State Hersey*, 838 F.3d at 350); see also Hackensack, 2022 WL 840463, at \*10-11. In fact, 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. For example, on page 208 of their post-trial brief, Respondents assert that "100%" will be passed through to consumers, Resp. Post-Tr. Br. at 208, yet earlier hedge that {

Having admitted to not calculating the amount of royalties that would be passed through, Respondents fail to satisfy their burden of producing evidence that the claimed efficiency would benefit consumers in the relevant market. *Otto Bock*, 2019 WL 2118886, at \*52-53 (holding that respondent had not demonstrated that "asserted efficiencies would benefit consumers in the [relevant market]" where "[respondent's expert] did not attempt to calculate an estimate of the efficiencies that would be realized by consumers"); *see also CCC Holdings*, 605 F. Supp. 2d at 74 (rejecting asserted cost savings efficiencies, noting that there was "no evidence to suggest that a sufficient percentage of those

savings will accrue to the benefit of the consumers to offset the potential for increased prices" and that "these advantages could show up in higher profits instead").

# E. Respondents Fail To Show that Any Elimination of Double Marginalization Is Verifiable, Merger-Specific, or Would Be Passed Through to Consumers

Respondents argue that the Acquisition will result in elimination of double marginalization ("EDM"), which they allege "is a well-documented efficiency from a vertical transaction that occurs when an upstream firm acquires a downstream firm to which it supplies inputs." Resp. Post-Tr. Br. at 211 (citing RPFF ¶ 1152). Specifically, Respondents state that their economic expert, Dr. Carlton, {

}. Respondents' EDM claim is neither supported by caselaw nor the record evidence.

### 1. Respondents' EDM Claim Is Unsupported by Caselaw

First, Respondents claim that "[c]ontrary to Complaint Counsel's present view, the elimination of double marginalization is a well-accepted efficiency of vertical integrations, as numerous courts have recognized." Resp. Post-Tr. Br. at 213-14. As discussed *supra*, § V, however, no court has held that efficiencies justify an otherwise anticompetitive merger, and the cases cited by Respondents do not support their argument. 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.

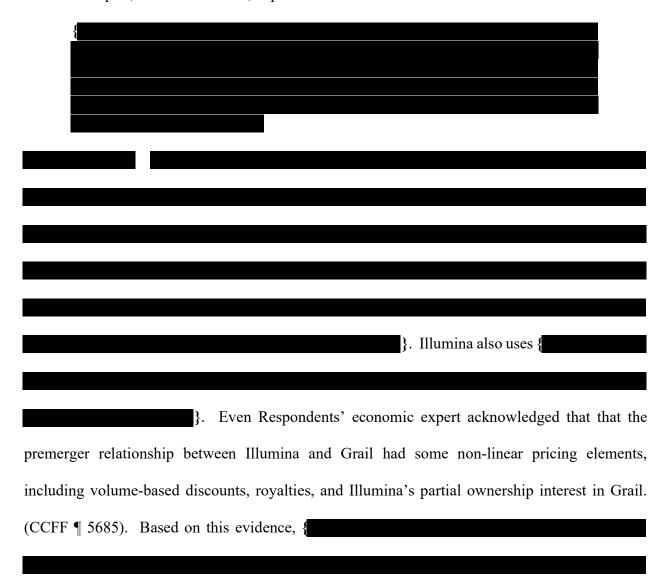
Moreover, to the extent the court discussed the existence of EDM in *AT&T*, it is because the government conceded that EDM would be generated in that transaction, *id.* at 197, whereas in this case, Complaint Counsel maintains that Respondents have failed to demonstrate that any EDM would be generated. <sup>150</sup>

#### 2. The Alleged EDM Is Not Verifiable

<sup>&</sup>lt;sup>150</sup> Relatedly, Respondents rely on inapposite cases involving Section 2 claims. *See* Resp. Post. Tr. Br. at 214 (citing *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 465 (7th Cir. 2020) & *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

have failed to identify the magnitude—let alone verify by reasonable means—their claimed EDM. *See Otto Bock*, 2019 WL 2118886, at \*50.

Besides not specifying the magnitude of EDM, Respondents also do not show that EDM is likely to result from the Acquisition. An EDM efficiency requires that double-marginalization exists pre-merger—if the parties have already eliminated the double-marginalization through other means, then a vertical merger results in zero (or at least reduced) EDM. As Complaint Counsel's economic expert, Dr. Scott Morton, explained:



}.
Respondents counter that Dr. Scott Morton's analysis "flies in the face of longstanding
economic literature, caselaw, and the Vertical Merger Guidelines." Resp. Post-Tr. Br. at 214. 151
But Respondents' cited materials merely suggest that EDM may result from some mergers—{
}. Respondents
have no answer to Dr. Scott Morton's analysis that, in this specific merger, EDM is unlikely to
result because Illumina and Grail were already engaged in {
the Acquisition. Indeed, her conclusion is consistent with {
}. Ultimately, it is Respondents' burden to establish the likelihood and magnitude of
a claimed EDM efficiency, Otto Bock, 2019 WL 2118886, at *49-50 (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.

<sup>&</sup>lt;sup>151</sup> To support their claim, Respondents cite the district court decision in *AT&T*. As noted *supra* § V.E.1., however, there the government conceded that EDM would be generated in that transaction. *See AT&T*, 310 F. Supp. 3d at 197 (D.D.C.).

## 3. The Alleged EDM Is Not Merger Specific

Even if Respondents' claimed EDM efficiency was verifiable, it is not merger specific because it could be achieved { As discussed above, record evidence, including testimony from Respondents' executives and economic expert, shows that Illumina and Grail engaged in { } prior to the Acquisition. See supra, § V.E.2; see also (CCFF ¶¶ 5683-90). Given that { was available to Illumina and Grail prior to the merger, they could { }. Thus, even if Respondents have not fully employed these { } pre-Acquisition, the availability of } means that Respondents *could* eliminate double marginalization absent the merger. (CCFF ¶¶ 5679-81, 5694). As Dr. Scott Morton explained, eliminating double marginalization without the merger would have been as simple as { \}. Therefore, Respondents have failed to prove that their EDM efficiency is not merger specific.

# 4. Respondents Have Not Shown EDM Would Be Passed Through To Benefit Consumers

Even if Respondents were able to establish verifiable, merger-specific EDM that would result from the Acquisition, Respondents have not shown that any EDM would be passed through to customers as required by the caselaw. *See Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.) (quoting *Penn State Hershey*, 838 F.3d at 350). Although Respondents claim more than

in EDM will benefit consumers, Resp. Post-Tr. Br. at 212-13, Respondents' expert admitted in his deposition that he was unable to estimate the percentage of EDM that will be passed through. (CCFF ¶¶ 5717-20). Specifically, Dr. Carlton testified that determining the amount of EDM that would be passed through to consumers would require the creation of a fully specified economic model, (CCFF ¶ 5718), but he acknowledged he did not create such a model in this case, (CCFF ¶ 5716). Absent evidence demonstrating EDM would be passed through, the existence of any EDM is irrelevant because Respondents cannot show it would offset the anticompetitive harm resulting from the Acquisition in the relevant market. See Otto Bock, 2019 WL 2118886, at \*52-53 (holding that respondent had not demonstrated that "asserted efficiencies would benefit consumers in the [relevant market]" where respondent's expert "did not attempt to calculate an estimate of the efficiencies that would be realized by consumers"); see also CCC Holdings, 605 F. Supp. 2d at 74 (rejecting asserted cost savings efficiencies, noting that there was "no evidence to suggest that a sufficient percentage of those savings will accrue to the benefit of the consumers to offset the potential for increased prices" and that "these advantages could show up in higher profits instead").152

## F. Respondents' Supply Chain and Operational Efficiencies Are Not Cognizable

Respondents argue that "[r]euniting Illumina and GRAIL will allow them to achieve significant supply chain and operational efficiencies." Resp. Post-Tr. Br. at 215. Respondents have failed to substantiate the likelihood, magnitude, merger-specificity, or costs of these claimed efficiencies such that it is possible to verify them by reasonably means.

<sup>&</sup>lt;sup>152</sup> In contrast, Complaint Counsel's economic expert did account for the possibility of EDM in her economic analysis and concluded that the Acquisition's

First, the likelihood and magnitude of the claimed efficiencies are not verifiable. Respondents argue that the "reunion of Illumina and GRAIL will allow GRAIL to benefit from Illumina's prices and relationships in areas of common products" as well as "allow GRAIL to benefit from Illumina's lab operations capabilities." Resp. Post-Tr. Br. at 216-17. The only quantification cited by Respondents in support of this efficiency is a single spreadsheet from Illumina cited in one footnote in the report of Respondents' economic expert, Dr. Carlton. *See* (RPFF ¶ 1166); Resp. Post-Tr. Br. at 218-19; *see also* (CCFF ¶¶ 5792-93). As Complaint Counsel's efficiency expert explained, {

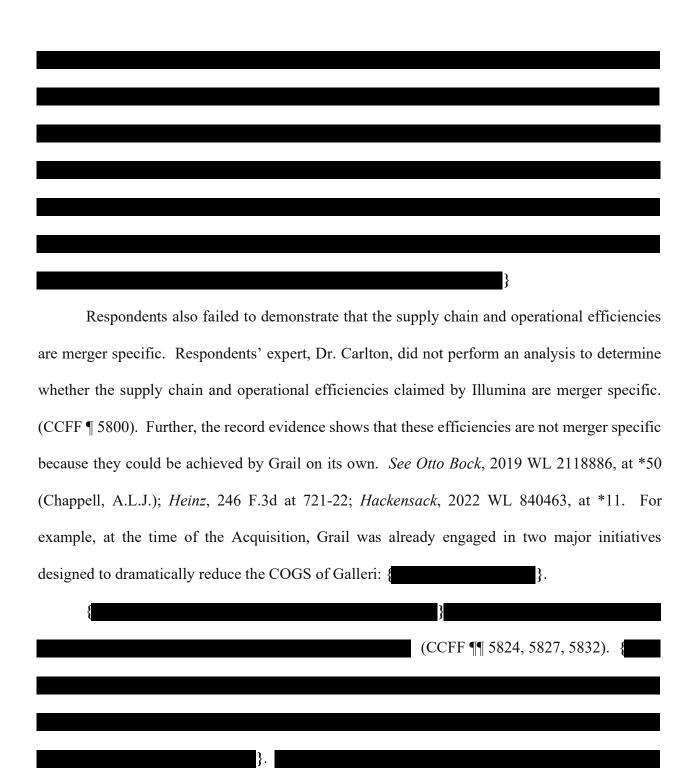
}. As this court

has explained, "it is incumbent upon the merging firms to substantiate efficiency claims," *Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.), and the absence of any additional details regarding the inputs or assumptions precludes the verification of this estimate. (CCFF ¶ 5791-92). Additionally, although the estimate was included in a footnote in his report, Dr. Carlton testified that he did not perform an independent quantification of variable cost savings from supply chain and operational efficiencies. (CCFF ¶ 5797). *See Otto Bock*, 2019 WL 2118886, at \*52-53 (Chappell, A.L.J.) (rejecting respondent's efficiencies argument where "the evidence fails to show that [the respondent's expert] independently verified the cost savings estimates in the financial model.").

Respondents counter that they "do not depend on either Dr. Carlton or the document he cited for this efficiency" and that the efficiency is support by "direct testimony" from fact

witnesses. Resp. Post-Tr. Br. at 219. Although several Respondent witnesses testified 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. *See, e.g.*, Resp. Post-Tr. Br. at 216-18 ("Grail would enjoy bigger discounts than it gets today"; "the cost of goods for the Galleri test would decrease;" "[w]e also would have the ability to have increased purchasing power;" "scale brings cost benefits"; "operational capabilities are benefits that Grail will enjoy"; "we believe that we will lower the facilities costs"). Therefore, the lay witness testimony provided no additional substantiation for the estimated savings.

Additionally, record evidence shows that these supply chain and operational efficiency claims were only developed in the course of litigation, and accordingly, merit further skepticism. *See Bazaarvoice*, 2014 WL 203966, at \*73 (quoting *Chi. Bridge*, 534 F.3d at 435) ("Consistent with *General Dynamics Corp.*, the probative value of post-acquisition evidence is particularly limited 'whenever such evidence could arguably be subject to manipulation.' This is especially true when the parties are aware of the government's scrutiny and the potential for a court challenge."). Notably, Respondents did not include efficiencies related to supply chain and lab operations in their Answer. (CCFF ¶ 5786). Further, in {



 $(CCFF \P 5829, 5833).$ 

Similarly, as part of its lab operations planning, {
} As Grail's CEO
testified at trial, Grail built the RTP lab 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 $\P$
5808).
As a result of these initiatives, Grail projected {
} 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. See Otto Bock, 2019 WL 2118886, at *50 (Chappell, A.L.J.); Heinz, 246 F.3d at 721-
22; Hackensack, 2022 WL 840463, at *11.

Additionally, Respondents have failed to demonstrate that a merger with Illumina would be the only means for Grail to achieve these supply chain and operational cost savings. Instead, record evidence shows that Grail viewed other life science companies as having superior production capabilities compared to Illumina. For example, {

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). *See Otto Bock*, 2019 WL 2118886, at \*52-53 (Chappell, A.L.J.).

# G. Respondents' Claimed Efficiency of International Expansion Acceleration Is Not Cognizable

Respondents assert that the Acquisition "will accelerate the international expansion of Galleri because it will put Illumina in a position to leverage its significant international resources for GRAIL." Resp. Post-Tr. Br. at 220 (citing RPFF ¶ 1168). Specifically, they claim that "Illumina will dramatically increase GRAIL's ability to access international markets and to achieve regulatory and payor approvals outside the United States." Resp. Post-Tr. Br. at 221. Respondents fail to demonstrate that this efficiency claim is verifiable, merger-specific, or would be passed through to consumers in the relevant market.

First, "[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 CC Post-Tr. Br. 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.").

Respondents also argue that such international expansion efforts nonetheless "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." Resp. Post-Tr. Br. at 223. This attempt to link an alleged out-of-market efficiency to the

<sup>153</sup> 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).

Respondents do not contest Complaint Counsel's allegation that "[t]he United States is the relevant geographic market to assess the competitive effects of the Acquisition." Complaint ¶ 37; Resp. Post-Tr. Br.

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.

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. *See Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.) (explaining the merging firm must substantiate "how and when each would be achieved (and any costs of doing so). 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 sum, as this court has explained, "[t]he law requires '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." *Otto Bock*, 2019 WL 2118886, at \*50 (Chappell, A.L.J.) (quoting *Heinz*, 246 F.3d at 721); *see also Wilh. Wilhelmsen*, 341 F. Supp. 3d at 72; *CCC Holdings, Inc.*, 605 F. Supp. 2d at 72-73. For the reasons discussed above, Respondents have failed to substantiate any of their efficiency claims sufficiently to verify by reasonable means their likelihood and magnitude, their timing and costs, their merger-specificity,

or their benefit to customers. Therefore, Respondents' claimed efficiencies are not a basis to justify this anticompetitive merger.

## VI. Respondents' Constitutional Challenges Are Meritless

Respondents attempt to cast doubt on the constitutionality of the Commission's structure and procedures. Respondents make three arguments, all of which miss the mark.

First, Respondents contend that this proceeding violates Article II of the U.S. Constitution because the President cannot "adequately oversee" the "faithfulness" of an FTC Administrative Law Judge ("ALJ"). Resp. Post-Tr. Br. at 232 (citing U.S. Const., art. II). This argument has been rightly, and repeatedly, rejected by the Commission. In 1-800 Contacts, the Commission correctly recognized that 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)). 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

<sup>&</sup>lt;sup>155</sup> 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.* <sup>156</sup> The Supreme Court took care to note in *Free Enterprise Fund* 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." 561 U.S. at 507 n.10 (citations omitted).

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). 157

These sound decisions of the Commission accord with 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<sup>158</sup>—"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, <sup>159</sup> "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, <sup>160</sup> "arguably would not be considered central to the functioning of the Executive

<sup>&</sup>lt;sup>157</sup> In a footnote, Respondents argue that protections granted by Congress regarding the removal of Commissioners also violates Article II. Resp. Post-Tr. Br. at 236 n.28. 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).

<sup>&</sup>lt;sup>158</sup> See 15 U.S.C. § 46(b) (describing the adjudicatory powers of the "Commission"); Reorganization Plan No. 4 of 1961 § 1(a), 26 Fed. Reg. 6,191, 75 Stat. 837 (providing that "the Federal Trade Commission . . . shall have the authority to delegate . . . any of its functions to a hearing examiner, or an employee or employee board").

<sup>&</sup>lt;sup>159</sup> See 16 C.F.R. § 0.14 ("Administrative law judges are officials to whom the Commission, in accordance with law, delegates the initial performance of statutory fact-finding functions and initial rulings on conclusions of law.").

<sup>&</sup>lt;sup>160</sup> See 1-800 Contacts, 2018 WL 6078349, at \*11 ("The Commission reviews the ALJ's findings of fact and conclusions of law de novo[.]") (citing 16 C.F.R. § 3.54(a)).

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).

The Fifth Circuit's split decision in *Jarkesy v. SEC*, 2022 WL 1563613 (5th Cir. May 18, 2022) does not compel a contrary conclusion. *Jarkesy* was decided on three grounds, only one of which has any relevance here. <sup>161</sup> Ignoring *Decker Coal* and over a dissent, the majority in *Jarkesy* held that the "statutory removal restrictions for SEC ALJs are unconstitutional." *Id.* at \*11. This holding was not based on any intervening Supreme Court precedent; it drew instead from the same Supreme Court cases that the Commission considered in rejecting similar Article II challenges. *See, e.g., 1-800 Contacts*, 2018 WL 6078349, at \*53-54 (citing *Free Enterprise Fund*, 561 U.S. 477 and *Lucia*, 138 S. Ct. 2044). The *Jarkesy* majority rested its holding on the premise that "SEC ALJs perform substantial executive functions." 2022 WL 1563613, at \*11. This renders *Jarkesy* inapposite, as FTC ALJs serve a purely adjudicatory function. FTC ALJs have no investigatory or enforcement powers, nor do they establish agency policies or priorities. *See* 15 U.S.C. § 57a; 16 C.F.R. §§ 0.14, 1.13, 1.13(i), 1.14, 1.25, & 1.26(d). Rather, in administrative adjudications before the Commission, an FTC ALJ functions solely as a judge, and the initial decisions of an FTC ALJ are purely recommendatory and do not bind parties unless and until the Commission

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Noting that the removability ground may not have sufficed to justify vacatur, the Fifth Circuit vacated the SEC's judgment in *Jarkesy* based on the Seventh Amendment and the non-delegation doctrine. 2022 WL 1563613, at \*13 ("We also hold that the statutory removal restrictions for SEC ALJs are unconstitutional, though we do not address whether vacating would be appropriate based on that defect alone."). Respondents waived these defenses by failing to plead them in their amended answer or argue them in their pre-trial and post-trial briefs. Regardless, the defenses would fail. Unlike the fraud claim at issue in *Jarkesy*, a proceeding to enjoin an anticompetitive merger that violates § 7 of the Clayton Act and § 5 of the FTC Act cannot be said to "arise at common law under the Seventh Amendment." *Id.* at \*4 (internal quotation marks omitted). Additionally, a Commission decision whether to pursue an enforcement action in federal court or in Part 3 constitutes a "forum choice" that is a classic exercise of prosecutorial discretion, which is an executive function and not a legislative one. *See Hill v. SEC*, 114 F. Supp. 3d 1297, 1313 (N.D. Ga. 2015), *vacated on other grounds*, 825 F.3d 1236 (11th Cir. 2016).

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."). The Jarkesy decision is no basis for second-guessing the conclusion reached by the Commission in 1-800 Contacts and Otto Bock (and consistent with the Supreme Court's decision in Free Enterprise Fund) that the removability of FTC ALJs passes constitutional muster.

Second, Respondents assert that the FTC adjudication process prescribed by Congress, namely the combination of "investigatory and adjudicatory functions," violates the Due Process Clause of the Fifth Amendment. Resp. Post-Tr. Br. at 236-37 & n.29 (citing U.S. Const. amend. V). This argument has also been rightly and repeatedly rejected by the Commission, as it runs contrary to nearly a hundred years of established precedent.

As the Commission observed in *North Carolina Dental*, "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

<sup>162</sup> The Supreme Court in *Withrow* elaborated on why administrative adjudicators are no more prone to unconstitutional bias or prejudgment than judges presiding over ordinary criminal or civil proceedings:

Judges repeatedly issue arrest warrants on the basis that there is probable cause to believe that a crime has been committed and that the person named in the warrant has committed it. Judges also preside at preliminary hearings where they must decide whether the evidence is sufficient to hold a defendant for trial. Neither of these pretrial involvements has been thought to raise any constitutional barrier against the judge's presiding over the criminal trial and, if the trial is without a jury, against making the necessary determination of guilt or innocence. Nor has it been thought that a judge is disqualified from presiding over injunction proceedings because he has initially assessed the facts in issuing or denying a temporary restraining order or a preliminary injunction. It is also very typical for the members of administrative agencies to receive the results of investigations, to approve the filing of charges or formal complaints instituting enforcement proceedings, and then to participate in the ensuing hearings. This mode of procedure does not violate the Administrative Procedure Act, and it does not violate due process of law.

421 U.S. at 56. See also In re Whole Foods Mkt., Inc. & Wild Oats Mkts., Inc., Docket No. 9324, 2008 WL 4153583, at \*3 (F.T.C. Sept. 5, 2008) ("The APA generally forbids a person from ruling on an adjudicative matter if that person engaged 'in the performance of investigative or prosecuting functions for' the matter or a factually related matter. This prohibition 'does not apply . . . (C) to the agency or a member or members of the body comprising the agency."") (alteration in original) (citation omitted) (quoting 5 U.S.C. §554(d)(2)).

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, <sup>163</sup> 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. <sup>164</sup> 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").

Third, Respondents maintain that it violates the Equal Protection Clause of the Fourteenth Amendment for this enforcement action to have been brought by the FTC rather than the Antitrust Division of the U.S. Department of Justice ("DOJ"). Resp. Post-Tr. Br. at 240–41 (citing U.S. Const. amend. XIV, § 1). Once again, Respondents' argument has been rejected by the Commission and the courts.

At the threshold, Respondents make the same crucial misstep that doomed a similar equalprotection 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

<sup>&</sup>lt;sup>163</sup> The Part 3 rules provide for the disqualification of any Commissioner "in accordance with legal standards applicable to the proceeding in which such motion is filed." 16 C.F.R. § 4.17(c).

Respondents cite unverified win-loss figures to suggest that the Commission prejudges appeals from initial decisions. Resp. Post-Trial Br. at 237-39. 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).

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

<sup>&</sup>lt;sup>165</sup> Respondents misconstrue the Court's reference to "rules [that] were changed after I came to the Federal Trade Commission because of rulings I continually made applying Federal Rule of Evidence." Resp. Br. at 243 (quoting Final Pretrial Hr'g Tr. 66). The Court's statement does not support Respondents' assertion that the Commission has "changed procedural rules when ALJs have ruled against it." *Id*.

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. 166

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'

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<sup>&</sup>lt;sup>166</sup> It is difficult to square Respondents' abstract complaints about the fairness of the Part 3 process with the due process they actually received: Respondents successfully introduced almost all of the thousands of their proposed trial exhibits, called eight expert witnesses and over a dozen other witnesses at the hearing, excluded evidence from a competitor to Grail, and submitted post-trial filings totaling over eight hundred pages (not including the post-trial reply filings due today).

<sup>&</sup>lt;sup>167</sup> Heightened review of a policy can be undertaken if a provision discriminates based upon a suspect classification or interferes with a fundamental right. *Mass. Bd. of Ret. v. Murgia*, 427 U.S. 307, 312-13 (1976). A suspect class is one "saddled with such disabilities, or subjected to such a history of purposeful unequal treatment, or relegated to such a position of political powerlessness as to command extraordinary protection from the majoritarian political process." *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 28 (1973). Respondents have not argued—nor could they—that merging parties (or companies in Respondents' industries) constitute a suspect class or that their consummation of a business acquisition is a fundamental right. Thus, rational basis review applies here.

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.").

# VII. Complaint Counsel's Case Rests on a Foundation of Credible Industry Participants and Respondents' Own Ordinary Course Documents

After 245 pages of misstatements and misrepresentations where Respondents fail to accurately address the relevant facts and legal standards, Respondents continue to obfuscate their lack of valid support by exaggerating the probative value of their own witnesses—all the while leveling inaccurate potshots at Complaint Counsel's witnesses and evidence. Resp. Post-Tr. Br. § VII. A peak behind Respondents' smokescreen reveals their charade. Respondents primarily relied on paid witnesses to support their case, calling 24 witnesses at trial, 21 of whom were financially bound to Respondents. Although Respondents submitted over 2,500 exhibits into evidence, they used only 13 ordinary course documents with their employee witnesses throughout the weeks-long trial. Instead, Respondents in large part had their witnesses take the stand and testify with the support of made-for-litigation demonstratives rather than ordinary course documents. To

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<sup>&</sup>lt;sup>168</sup> Complaint Counsel addresses the factual flaws in Respondents' argument in Complaint Counsel's responses to their proposed Conclusions of Law and Findings of Facts. For brevity, Complaint Counsel only highlights a select cross-selection of illustrative examples pervasive throughout Respondents' conclusions and findings.

Respondents called four third-party witnesses, one of whom—Matt Strom—was Grail's paid consultant during the Acquisition. (Strom (Morgan Stanley) Tr. 3473). Of the remaining three witnesses, Respondents called Konstantin Fiedler, FMI's Chief Operating Officer, who

other witnesses Jorge Velarde and Dr. Cance (who was also called by Complaint Counsel).

<sup>&</sup>lt;sup>170</sup> Respondents then cite to these made-for-litigation documents in their findings of fact as evidentiary support for their proposed findings in direct violation of this Court's order. *See, e.g.*, (Response to RPFF ¶¶ 368.1, 422, 430.1, 439.1, 442, 446, 459).

Throughout their briefing, Respondents repeatedly seek to characterize their witnesses' testimony as "uncontroverted" as if by sheer force of repetition, they can overcome the actual record in the case. Instead, as Complaint Counsel's Reply Brief and Responses to Respondents' Factual Findings show, Respondents' testimony was time and again shown to be either self-serving speculation without support or foundation, or contradicted by Complaint Counsel's witnesses and Respondents' normal course documents and admissions.

For example, Respondents cite to their witnesses throughout their briefing to support their claim that "no other test like [Galleri is] commercially available or even in development," ostensibly arguing that Galleri resides in a market of one. See, e.g., Resp. Post-Tr. Br. at 4; (Cote Tr. 3727). Grail's own S-1 statement, however, directly contradicts this—identifying Exact, Guardant, Helio, and Singlera (among others) as competitors in its filing to the Securities in Exchange Commission. (PX4082 (Grail) at 167, 211 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)). Respondents likewise rely heavily on their witnesses to support their contention that Exact/Thrive's CancerSEEK test is not sufficiently developed to pose a competitive threat to Galleri. Resp. Post-Tr. Br. at 36-37. Again, Grail's ordinary course documents beg to differ. (PX4443 (Grail) at 003 (Email from A. Chen, Grail, to J. Ofman, Grail, Jun. 13, 2020) (in camera)). And in response to the competition threat from Exact/Thrive, { } (PX4456 (Grail) at 013 { { (in camera)). Respondents' documents do not fit the story Respondents wish to tell this Court, so instead Respondents ask this Court to ignore their documents and believe the post-Acquisition testimony of their biased, paid witnesses.

Throughout this litigation, Respondents have sought to make this case a trial-by-expert, pushing past evidentiary rules and this Court's orders in the process, in a futile attempt to plug the holes in their case. Respondents initially attempted to impermissibly add the expert report of Dr. Serafin into evidence despite not providing adequate notice under the rules. *See* Order Memorializing Bench Rulings, *In re Illumina, Inc. and GRAIL, Inc.*, Docket No. 9401, at 2 (Aug. 25, 2021) (excluding the declaration and deposition of George Serafin). At trial, Respondents presented the biased testimony of their experts (including the testimony of Dr. Abrams who sat on one of Grail's advisory boards) that was in large part unsupported and/or contradicted by industry participants best situated to testify as to market realities. *See, e.g.*, (Response to RPFF ¶ 161, 191, 472, 587, 589-92, 594.2, 596, 598-99, 600.3, 600.4, 602, 604, 604.1, 652, 667-69, 672.1, 672.2, 673-74) (providing illustrative examples of unsupported claims); (Response to RPFF ¶ 2028-39) (explaining Dr. Abrams entanglements with Grail).

As explained extensively in Complaint Counsel's Responses to Respondents' Proposed Findings of Fact, Respondents' expert testimony is not credible and often directly contradicted by statements of industry participants and, at times, by Illumina and Grail's own statements. For example, Respondents rely heavily on Dr. Cote to establish that {

Resp. Post-Tr. Br. at 77. However, just two months prior in February 2022, Illumina represented to a federal court that BGI's technology is "unproven and immature." Pl.'s Reply in Support of Mot. for Permanent Inj.,

*Illumina, Inc. v. BGI Genomics Co., Ltd.*, Docket No. 3:19-cv-03770, at 10 (N.D. Cal. Feb. 16, 2022).<sup>171</sup>

Respondents' gamesmanship continued post-trial when, instead of substituting the testimony of Dr. Katz for Dr. Willig per this Court's Order, *see* Order Granting Respondents' Motion for Leave to Substitute a Replacement Expert Witness, *In re Illumina, Inc. and GRAIL, Inc.*, Docket No. 9401, at 2 (Oct. 12, 2021), Respondents cite to Dr. Katz in *addition* to Dr. Willig's testimony throughout the post-trial briefing, even though the opinions expressed by Dr. Katz in his trial deposition impermissibly exceeded the scope of Dr. Willig's opinion. *See* (Response to RPFF ¶ 2040-56).

Failing to plug all the holes in their sinking ship through experts, and unable to find ordinary course documents to buttress their claims, Respondents instead turn to citing unreliable screenshots and websites, *see*, *e.g.*, (Response to RPFF ¶ 587, 590, 596, 602, 642.2), and even, at times, misciting the underlying source. *See*, *e.g.*, (Response to RPFF ¶ 159.2, 468, 612, 624, 709.3, 735, 758, 784.6, 801.1, 998.5, 1047.4, 1699, 1812). In contrast, Complaint Counsel presented the testimony of 11 third-party witnesses including a witness from the American Cancer society, six of Grail's MCED test rivals, and an NGS platform provider. Each third party's testimony was corroborated not only by the other MCED test developers, but by the witnesses' ordinary course documents as well as Complaint Counsel's expert witnesses. Moreover, as explained above, Respondents' own documents corroborate the testimony of each MCED test developer who all testified to the following: that they have invested substantial money into the

<sup>&</sup>lt;sup>171</sup> In addition to being factually incorrect, Respondents' citations to their experts at times violates this Court's order limiting expert testimony to opinion testimony. (Response to RPFF ¶¶ 81, 82-107, 122-39, 422, 444, 457, 470-71, 580, 588, 784, 943).

research and development of MCED tests; that each MCED test is intended to detect a high number of cancers in an asymptomatic patient population; that each MCED test developer competes head-to-head with Grail's Galleri test and intends to continue to compete in the future; and that each MCED test is dependent on Illumina's NGS platform. (CCFF §§ V, VI, VII.B.3-5).

Respondents, however, ask this Court to ignore the testimony of Grail's competitors (and Illumina's own customers) because they are competing with Grail and, thus, cannot be trusted. Putting Respondents' nonsensical argument aside, the consistency of Complaint Counsel's witnesses' testimony, which is supported by Respondents' own documents, establish MCED test developers' credibility.

Respondents also ask this Court to engage in a hyper-technical misreading of caselaw that would effectively preclude vertical enforcement. Complaint Counsel's legal theories, in contrast, are grounded in decades of legal precedent—including Supreme Court precedent, economic principles as established by the testimony of our three experts, and well supported by both testimony and documents. This Court should follow the well-trodden path of its sister courts and find that post-Acquisition Illumina and Grail will have the ability and incentive to disadvantage its rivals and has a substantial likelihood of lessening competition.

# VIII. Divestiture Is the "Natural Remedy" for Illumina's Illegal Acquisition

Respondents object to the divestiture of Grail's ongoing business, arguing that such a remedy would be "overbroad and unnecessarily punitive." Resp. Post-Tr. Br. at 277. 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").

Respondents also 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 *infra*, § V, and in Complaint Counsel's post-trial brief, *see* CC Post-Tr. Br. § 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

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<sup>&</sup>lt;sup>172</sup> Respondents also claim that undoing the Acquisition will deny Grail critical funding. *See* Resp. Post-Tr. Br. at 279-80. Prior to the Acquisition, however, 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). Mere weeks before the Acquisition, Grail

<sup>{ (</sup>CCFF ¶ 5904). 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).

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.

Respondents also argue that, for reasons completely under their own control, "divestiture would be fundamentally inequitable to Respondents." Resp. Post-Tr. Br. at 280. Specifically, Respondents argue that because they have already closed the Acquisition, a divestiture would "affect private property interests." Resp. Post-Tr. Br. at 280. This, however, runs contrary to well established 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

<sup>&</sup>lt;sup>173</sup> Respondents also claim that it would be unfair to unwind the Acquisition because the Commission "withdrew its preliminary injunction and allowed the Transaction to close under U.S. law." Resp. Post-Tr. Br. at 280. It appears Respondents misunderstand the purpose of preliminary injunctions. As the Commission explained in its motion to dismiss the preliminary injunction in federal court:

<sup>[</sup>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.

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)).

#### **CONCLUSION**

For the foregoing reasons, the evidence presented at trial and admitted into the record establishes that Illumina's acquisition of Grail, as consummated on August 18, 2021, violated Section 7 of the Clayton Act and Section 5 of the FTC Act, as alleged in the Complaint, and justifies entry of the Proposed Order that was enclosed with Complaint Counsel's post-trial brief and any such other relief that the Court deems necessary and proper.

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).

### **PUBLIC**

Dated: June 2, 2022 Respectfully submitted,

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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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The Honorable D. Michael Chappell Administrative Law Judge Federal Trade Commission 600 Pennsylvania Ave., NW, Rm. H-110 Washington, DC 20580

I also certify that I caused the foregoing document to be served via File Transfer Protocol to:

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