PUBLIC

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

RESPONDENTS' PRETRIAL BRIEF

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PRELIMINARY STATEMENT

This case involves a vertical merger that will save thousands of lives. In the United States alone, cancer kills more than 600,000 people annually. The transaction will accelerate the development, approval and adoption of Galleri, a revolutionary blood test that can simultaneously detect more than 50 cancer types, over 45 of which have no approved screening test today. The test allows doctors to catch those cancers at earlier stages, when cancers are more likely to be cured. Complaint Counsel's challenge to the transaction, which would undeniably delay Galleri and thus deprive patients of this acceleration, is speculative and baseless. Longstanding legal precedent, agency guidelines and economic literature recognize that vertical mergers of this kind generate efficiencies that promote consumer welfare and generally do not raise competitive concerns except in very limited circumstances. The evidence will show that those limited circumstances are not present here.

Illumina is a leading provider of sequencing products for genetic and genomic analyses. Its mission is to improve human health by unlocking the power of the genome. Illumina founded GRAIL five years ago with the goal of developing an early screening test for multiple cancers. In 2017, Illumina reduced its investment in GRAIL to allow it to procure the investments needed for the extensive, population-scale clinical trials required to create an "atlas" of cancer signals in the blood, and the attendant state-of-the art machine learning platform to interpret those signals, enabling asymptomatic early cancer screening tests. Since that time, GRAIL has developed an early screening test, Galleri, that can simultaneously screen for more than 50 cancers in asymptomatic patients who have no signs of cancer. GRAIL launched Galleri as a laboratory developed test ("LDT") in the United States in April 2021, but is still many years from being able to commercialize Galleri at a wide scale. In short, GRAIL is a discovery and development company that has accomplished the goals contemplated by Illumina when it created

GRAIL. Illumina stands poised to help GRAIL bring those benefits to the public as quickly and efficiently as possible.

Grail and Illumina have never been completely separate. Before the transaction, Illumina maintained approximately a 12% equity stake in GRAIL, on a fully diluted basis, and, under its existing supply agreement with GRAIL, is entitled to a percentage of GRAIL's net revenues in perpetuity. The transaction fully reunites Illumina and GRAIL at a critical juncture. While GRAIL has made progress in developing Galleri, it faces significant hurdles, including obtaining regulatory approval, payor reimbursement and production and distribution of its test at scale. Illumina is uniquely situated to accelerate the widespread adoption of Galleri, and reach more patients faster. The combined company will launch a new era of cancer screening, accelerating commercialization and adoption of GRAIL's transformative multi-cancer screening test at scale. Galleri has the potential to reduce the cancer burden in the U.S. and worldwide—this transaction thus means saving thousands of lives and billions of dollars by reducing that burden sooner and at lower costs.

Market Definition. Complaint Counsel is required to properly define relevant upstream and downstream antitrust product markets. Complaint Counsel does not even allege a relevant upstream market, and its alleged downstream "multi-cancer early detection", or "MCED", market has no grounding in the evidence. As Complaint Counsel acknowledges, there are no commercially available MCED tests besides Galleri. Complaint Counsel asserts that there are many companies developing tests that will eventually have performance attributes similar to Galleri, and those tests, when launched, will be close substitutes with Galleri, but not with other modalities of cancer screening. These assertions have no basis. As third party testimony will show, along with the expert testimony of Dr. Richard Cote, a leader in the field of cancer

research, no other company has developed a test that can identify such a broad range of cancers in asymptomatic patients as can Galleri. The so-called close substitutes that Complaint Counsel identifies have, charitably, shown the potential to screen for only ten cancers, and are primarily focusing on cancers with existing standard of care screening tests. The evidence will show that the alleged market includes tests that are not plausibly close substitutes for Galleri, while excluding screening modalities that will likely exert competitive pressure on MCED tests. Such vague and incoherent line-drawing results in an alleged market that is simultaneously overly broad and overly narrow and that cannot satisfy Complaint Counsel's burden of proving a relevant product market.

Further, rather than define an upstream relevant product market (as it is required to do), Complaint Counsel asserts that there is a "related product" market comprising only Illumina's NGS systems. That contention ignores the evidence of growing competition from NGS and non-NGS based competitors, described below. By failing to account for this competition, Complaint Counsel cannot satisfy its burden of proving a relevant upstream product market.

Alleged Foreclosure. There is no basis for Complaint Counsel's prediction that, in the foreseeable future, there will be tests on the market that could be expected to divert a material volume of sales from Galleri. The screening tests in development that Complaint Counsel identifies are highly differentiated from Galleri in material ways and, given that differentiation, there is no ground to predict those tests, if they launch at all, will develop into substitutes from which hypothetical foreclosed sales would likely divert to Galleri. The absence of evidence of likely material diversion between Galleri and the tests identified by Complaint Counsel is alone fatal to Complaint Counsel's theory of the case.

Nor is there a basis to predict—as Complaint Counsel must show to satisfy its burden—that Illumina would destroy its long-standing reputation as a trusted supplier of NGS systems, and put its profitable upstream sales at risk, by attempting to foreclose its clinical oncology customers, some of which are Illumina's largest customers. Further, Complaint Counsel ignores the intensifying, near-term competitive pressure on Illumina's NGS business (even while engaging in rank speculation about purported future harms in the alleged downstream market). The evidence will show that both established players and credible new entrants are investing in developing sequencing systems that will target the early cancer detection space, as well as other profitable downstream applications. In fact, increasing upstream competition is one of the reasons Illumina chose to purchase GRAIL. And the evidence of highly dynamic upstream competition continues to mount—just last month, Pacific Biosciences of California, Inc. ("PacBio"), a leading supplier of long-read NGS systems, announced that it will acquire Omniome, Inc., a developer of an emerging high-accuracy short-read NGS technology, for $800 million, and will target early cancer screening[1]—a fact that Complaint Counsel glosses over, only mentioning the acquisition in a single sentence in a footnote.[2] These well-funded upstream innovators are poised to take share from Illumina, and, as Illumina witnesses will testify (and its internal documents demonstrate), Illumina fully expects that it will have to compete intensely with upstream rivals by continuing to drive down costs and offer high quality, innovative solutions and services to its clinical oncology (including cancer screening) customers. In fact, other competitors are getting ready to compete, including Singular

[1] *Pacific Biosciences Signs Definitive Agreement to Acquire Omniome*, July 20, 2021, *available at* https://www.pacb.com/press_releases/pacific-biosciences-signs-definitive-agreement-to-acquire-omniome/ (last visited Aug. 18, 2021).

[2] Complaint Counsel's Pre-Trial Brief, dated August 13, 2021 ("CC Br.") at 101 n.570.

Genomics Systems, Inc. ("Singular"), BGI Genomics ("BGI"), Omniome and others. Indeed, test developers such as Natera, Inc. ("Natera") are already working with BGI in China—and will do so in the U.S. as soon as they are able to. There is no credible basis to ignore this evidence of dynamic upstream innovation and competition.

Further—and directly contrary to Complaint Counsel's speculation that the merger will disincentivize investment in NGS cancer screening—the evidence will show that there has been a flood of investment into liquid biopsy cancer screening test development, with much of that activity occurring after the merger was announced just over a year ago. Shortly after the merger was announced, analysts predicted that the deal would *accelerate* investment and innovation in the space, with one observing that "the recent acquisition of GRAIL by ILMN has catalyzed the excitement in the market to new highs – even ahead of our prior expectations", and "there is an expectation that more companies will increasingly pursue liquid biopsy screening as ILMN's acquisition of pre-revenue GRAIL has 'validated' the liquid biopsy early detection theses."[3] Those predictions have borne out. For example, in the months since, Exact Sciences Corp. ("Exact") purchased Thrive Earlier Detection Corp. ("Thrive") for $2.1 billion, Caris Life Sciences Inc. ("Caris") received an investment of $830 million to support its cancer screening test and [redacted]. [4] As Respondents' economic expert Dr. Robert Willig will testify, such

[3] RX1096 at 3 (SVBLeerink, Life Science Tools and Diagnostics Report, dated Oct. 2, 2020).

[4] *E.g.*, RX3196 at 1 (Mohammad Shayan Javeed, Exact Sciences Closes Acquisition of Thrive Earlier Detection, S&P Global Market Intelligence, dated Jan. 5, 2021); RX3042 at 1 (Molika Ashford, Caris Life Sciences, Fueled by New Funding, Plans to Expand Liquid Biopsy Testing, Precision Oncology News, dated May 19, 2021); [redacted]

investment activity would defy economic logic if there were merit to Complaint Counsel's speculative theory of innovation harm and long-term lock-in.

The Open Offer. Illumina has every incentive and intent to ensure that the GRAIL acquisition does not adversely affect any of its clinical oncology customers. Nevertheless, to erase any doubts, Illumina has offered those customers comprehensive, long-term commitments that fully address the alleged competitive concerns (the "Open Offer"). In the preamble to the Open Offer, Illumina expressly states that its purpose is "to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in Next-Generation Sequencing ('NGS')."[5] The trial evidence, including the testimony of remedies expert Margaret Guerin-Calvert, will show that the Open Offer does just that, by providing robust guarantees pertaining to access, pricing and quality of Illumina's NGS systems on terms that are equal to or better (for the customer) than those that Illumina's oncology customers have now. Specifically, the Open Offer guarantees that:

- Under a 12-year supply agreement, customers will have uninterrupted supply of the sequencing instruments and consumables that they use;
- During that 12-year term, Illumina will not increase the price of any of the supplied sequencing instruments or consumables;
- Far from increasing the price, by 2025, Illumina will decrease the cost of sequencing on Illumina's highest throughput sequencing instrument, using the highest throughput consumable, by at least 43% for all customers, regardless of application or use case;
- All customers shall receive "universal pricing" for any new sequencing product, and customers shall receive access to the same sequencing products at the same pricing as GRAIL under a "most-favored nations" clause;

[5] RX3544 at 1 (Illumina Open Offer) at 1; *also available at* https://www.illumina.com/content/dam/illumina-marketing/documents/applications/cancer/illumina-open-offer.pdf.

- Illumina will not discontinue any sequencing product supplied for a 12-year term as long as the customer continues to purchase that product;
- To the extent Illumina receives confidential information from any customer, Illumina will not share that information with GRAIL;
- Illumina will provide any documentation or information reasonably required to seek FDA approval or FDA marketing authorization to sell a clinical test using the sequencing products supplied under the agreement;
- Any customer who wants to develop an *in vitro* diagnostic ("IVD") distributable kitted test using Illumina's FDA-regulated ("Dx") systems may enter into a separate agreement with Illumina under any one of three standard contracts;
- An annual audit will be conducted by an independent third-party auditor confirming compliance with the terms of the supply commitments; and
- Disputes on supply terms will be adjudicated through baseball-style arbitration, and Illumina must continue to supply products to the customer during the pendency of any such dispute.

These binding, irrevocable commitments are publicly available on Illumina's website[6] and open for a period of six years once the Open Offer becomes operative.

Complaint Counsel asserts that [redacted] has executed the Open Offer."[7] This is a distortion of the facts. [redacted]

[6] *See* RX3365 (Illumina, Oncology Contract Terms) at 1; *also available at* https://www.illumina.com/areas-of-interest/cancer/test-terms.html?SCID=2021-270ECL5522.

[7] CC Br. at 5.

[8] [redacted]

[redacted] Further, given that Open Offer was published only months ago and customers have *six years* to accept it from close, it should be no surprise that customers see no urgency to signing it.

Complaint Counsel's criticisms of the Open Offer are based entirely on assertions by certain Illumina customers whose representatives testified that they view the Open Offer as insufficient to prevent them from being disadvantaged post-merger. The evidence will show that these purported concerns are based on unfounded speculation about theoretical ways Illumina could circumvent the Open Offer that are not plausible and are fully addressed by the Open Offer's audit and arbitration provisions. The trial evidence will also show that these witnesses, and their purported concerns, simply are not credible; in negotiations with Illumina, they have made patently unreasonable demands that are unrelated to any viable foreclosure concern, such as access to GRAIL intellectual property that they would never receive absent the transaction. Such complaints do not reflect any good-faith concern about foreclosure, but a desire to impede GRAIL from becoming a more effective competitor through the efficiencies of the merger. Complaint Counsel also fails to account for the reputational consequences Illumina would face were it to backtrack from such public commitments. *See United States v. AT&T Inc*., 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018), *aff'd sub nom. United States v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019) ("Given its trial presentation, I am hard-pressed to conclude that AT&T

[9] [redacted]

[10] [redacted]

would (much less could) retreat from the commitment in light of the apparent reputational costs of doing so—costs that would imperil future negotiations in a marketplace with repeat players.").

Complaint Counsel thus has no credible basis to discard the robust contractual commitments provided in the Open Offer. Complaint Counsel's objections to the Open Offer are the sort of boilerplate objections that could be made with any contract or behavioral remedy, even though the most analogous legal authority (and the only decision involving a challenge to a vertical merger in the last 40 years) relied on similar commitments in rejecting a vertical merger challenge. *Id.* Similar to the arbitration offer in *AT&T*, the Open Offer "will have real world-effects" and puts the merging parties' "'money where [their] mouth is' in showing that the proposed merger, far from being aimed at 'doing any of the things that the government alleges,' is instead a 'vision deal' being pursued to achieve 'lower prices, improved quality, enhanced service, and new products.'" *Id.*

Procompetitive Benefits. While the FTC's allegations of harm are speculative and improbable, the procompetitive benefits arising from the reunion of Illumina and GRAIL are concrete and substantial. Most critically, the transaction will enable GRAIL to get its life-saving test to more patients, in the U.S. and globally, more quickly, and at lower prices than GRAIL could achieve absent the transaction. The impact of such acceleration cannot be overstated— the merger will lead to tens of thousands of additional lives being saved, and to substantial cost savings for consumers and healthcare systems. This acceleration will also pave the way for other test developers to obtain regulatory approvals, reimbursement and adoption of NGS-based multi-cancer screening tests. The merger will thus save lives and encourage innovation in cancer screening.

These important benefits arise from a number of efficiencies, including:

- *Accelerating FDA Approval and Medicare Reimbursement*. FDA approval is essential to scale Galleri and will be an enormous undertaking. The FDA has never even considered a multi-cancer screening test before, much less one that covers 50 cancers. [redacted] Illumina brings significant regulatory and quality resources with deep experience in obtaining FDA approval for NGS diagnostic products. Illumina will be able to leverage these resources to accelerate GRAIL's submission activities, minimize the chance of error, and speed up FDA review time to result in earlier approval for Galleri. Moreover, because it is unlikely that Galleri will be able to obtain Medicare coverage without FDA approval, accelerating FDA approval will accelerate Medicare coverage, which is critical for Galleri to achieve widespread adoption in the U.S.

- *Accelerating Private Insurance Reimbursement*. Illumina has unique experience obtaining reimbursement for NGS-based products, and has it set the standard in value-based healthcare through partnerships with insurers for clinical tests. [redacted] Illumina will leverage its capabilities to accelerate obtaining reimbursement for GRAIL's tests from private insurers. [redacted] This will vastly accelerate access to Galleri for U.S. consumers.

- *R&D Efficiencies*. The combination of Illumina's expertise in sequencing-based solutions and molecular biology with GRAIL's machine learning capabilities and repository of clinical data will help accelerate new breakthroughs in oncology and other fields. These efficiencies are potentially enormous and far from speculative, as history demonstrates. When Illumina acquired Verinata Health, Inc. ("Verinata")—through which it vertically integrated into the downstream market for non-invasive prenatal testing ("NIPT")—over 100,000 expectant mothers had taken Verinata's NIPT test. In a handful of cases, a signal was detected in the mother's blood that was initially believed to be a false signal indicating a genetic abnormality in the fetus. After the acquisition, scientists at Illumina gained access to and analyzed that data, discovering that the NIPT test had detected circulating tumor DNA fragments present in the mother's bloodstream. Verinata's NIPT test had, incidentally, detected cancer in the blood, albeit at a late stage. From there, Illumina set out to achieve one of the most critical goals of cancer care—detecting cancer in the blood at its earliest stages. It is from that discovery, arising from R&D efficiencies created as a result of the vertical acquisition of Verinata, that Illumina formed GRAIL.

- *Elimination of Double Marginalization ("EDM") and Royalties*. As the Vertical Merger Guidelines note, "vertical mergers often benefit consumers through the elimination of double marginalization, which tends to lessen the

risks of competitive harm."[11] Here, absent the transaction, Illumina and GRAIL would continue to each separately charge a mark-up over their costs, resulting in two margins (Illumina's on NGS products; GRAIL's on its tests) reflected in the price for GRAIL's tests. The merger will eliminate this double margin, with the savings passed through to consumers in the form of lower prices for Galleri, which will increase output and save lives. In addition to these well-recognized EDM benefits, the merger will effectively eliminate a portion of a royalty that GRAIL would otherwise owe Illumina on its future revenues, resulting in additional cost savings.

- *Supply Chain and Operational Efficiencies*. [redacted] Illumina will accelerate and de-risk this process. It has the global operational infrastructure and experience operating regulated manufacturing and laboratory facilities to assist GRAIL in commercializing its tests at scale, in compliance with the quality and safety standards required by regulators. Unlike GRAIL, Illumina has significant experience running high throughput, high-complexity laboratory services operations. Illumina has been running such services since 2002, with peak staffing of over 300 laboratory personnel. Illumina has three clinical testing laboratories, two in California, which are CLIA-certified, and one in the United Kingdom. Through its Illumina Lab Services division, Illumina offers clinical sequencing services, including NIPT testing and direct-to-consumer ("DTC") genomic testing, as well as, more recently, COVID testing. Illumina has developed deep competencies and know-how relating to laboratory automation, training highly skilled laboratory staff, efficient capacity utilization, error and sample requeue minimization, and workflow optimization. Illumina is one of the few companies in the world that has such extensive experience and capabilities in operating laboratories to process diagnostic tests at scale. Illumina's operational and commercial infrastructure will allow GRAIL to make its test more widely available at a faster rate and at lower costs.

Contrary to Complaint Counsel's arguments, these important benefits are merger-specific. [redacted] The trial evidence, including testimony from

[11] RX3701 at 34 (U.S. Department of Justice and Federal Trade Commission. Vertical Merger Guidelines, dated June 30, 2020).

Respondents' reimbursement expert Patricia Deverka, will show that the institutional expertise, experiences and competencies that Illumina will use to aid GRAIL in these efforts will minimize the chances of delays, and maximize the chances of accelerating wide-scale access to Galleri by U.S. consumers (and globally).

Further, there is no basis to conclude, as Complaint Counsel speculates, that the parties would achieve these benefits absent the merger. Complaint Counsel simply ignore their burden to show that alternatives are "practical", rather than hypothetical. Illumina has no history of providing such extensive development and go-to-market services as a third-party consultant. Nor does any similarly situated company. As both Illumina and Illumina customer witnesses will testify, Illumina is not involved in the development or regulatory efforts of its clinical customers in any material way. And Illumina's clinical customers, including GRAIL, do not and would not share proprietary information relating to their tests with Illumina. Without access to such data, Illumina cannot materially accelerate GRAIL's regulatory, payor and commercialization efforts, nor achieve the type of R&D efficiencies that Illumina has achieved in the past, such as from the Verinata acquisition, from which GRAIL was formed.

The evidence will show that the merger is necessary to eliminate these barriers to collaboration between Illumina and GRAIL in order to unlock the enormous, life-saving efficiencies that this procompetitive reunion will create. Complaint Counsel's attempt to challenge that reunion is misguided and baseless. Accordingly, judgment should be entered for Respondents.

BACKGROUND

A. Illumina

Illumina makes and sells sequencing instruments and consumables for next generation sequencing ("NGS") systems.[12] Illumina's NGS platforms may be used for a variety of applications, including basic and translational research for genetic and genomic analyses, reproductive health, genetic health and oncology.[13] Illumina's core strategy is to support expansion of sequencing applications and use cases to catalyze greater NGS adoption to unlock the power of the genome. Illumina has long pursued this strategy by driving down the cost of sequencing and improving its NGS systems and workflows.[14] Illumina's innovation in its NGS platform encourages the use and development of NGS tests by both research and commercial labs and clinical diagnostic companies.[15] Illumina firmly believes that it benefits when multiple innovators develop NGS tests for emerging applications, such as cancer screening, for which NGS is not yet an accepted modality.

NGS is a relatively new technology platform. In 2003, when Illumina was a fledgling company, it cost more than $100 million to sequence the complete human genome as part of the Human Genome Project.[16] In 2006, Illumina bought Solexa, its first major acquisition. Before the Solexa acquisition, Illumina was an array company and did not have any

[12] RX3361 at 7 (Illumina, Inc., Form 10-K for the fiscal year ending January 3, 2021, dated Feb. 16, 2021).

[13] *Id.*

[14] RX3833 (deSouza (Illumina) Dep.) at 278:13-18 ("[A]t Illumina we've reduced the cost of sequencing a lot over the years. That's our whole strategy around democratizing access to genomics.").

[15] RX3361 at 9-11 (Illumina, Inc., Form 10-K for the fiscal year ending January 3, 2021, dated Feb. 16, 2021).

[16] [redacted]

sequencing offering. Illumina's post-acquisition advancement of Solexa's technology enabled it to launch new and improved sequencing products by taking promising Solexa intellectual property and investing Illumina's R&D, engineering and manufacturing resources, commercial acumen and significant technical expertise, which it has continued to advance in the years since. Solexa's sequencing technology now forms the basis of Illumina's core SBS technology, which has driven down the cost of sequencing a human genome 4,000-fold. At the time of the Solexa acquisition, the cost of sequencing one billion base pairs (one gigabase) was more than $300,000. In the years since, Illumina has invested billions in R&D and driven innovation in NGS, bringing the cost of sequencing a complete genome down to less than $1,000, and less than $8 per gigabase.[17] It is part of Illumina's DNA, so to speak, to continuously improve its systems and to continuously drive down the cost of sequencing. In fact, Illumina drove down the cost of sequencing so substantially that this cost reduction was referred to as "Flatley's Law", after Illumina's then CEO.

These reductions in the cost of sequencing have led to the explosion of downstream applications that use NGS instruments and consumables. Applications for sequencing that were unimaginable even a few years ago have been made possible by Illumina sequencers. Illumina's contributions to the acceleration of sequencing technology have received widespread recognition, earning Illumina awards such as Time Magazine's 2021 "100 Most Influential Companies", Forbes' "The Just 100" in 2021 and "Most Innovative Companies" in multiple years, a Life Sciences Leadership Award for Jay Flatley in 2017 and recognition by

[17] *See* RX3515 at 3-4 (National Human Genome Research Institute, DNA Sequencing Costs: Data); RX3864 at ¶ 22 (Carlton Report).

MIT as a "World's Smartest Company".[18] It has carefully cultivated a reputation for NGS innovation and creating the tools to address the world's most serious diseases.[19]

As Illumina has innovated, NGS sales have grown over time and are expected to continue to grow; [redacted][20] It is widely understood that the future of NGS is in clinical diagnostic applications, where NGS has enormous potential to improve human health and disease management. To date, NGS has only scratched the surface of that potential.

To serve the clinical applications of today and in the future, Illumina has spent the last decade transforming itself from an NGS innovator focused primarily on serving research markets, into a supplier of NGS systems that can also be used to transform disease management through cutting-edge clinical testing. To do so, Illumina has had to build the R&D, manufacturing, quality control and other capabilities that are necessary to serve customers developing tests and positioning to operate in highly regulated clinical markets at scale. Illumina recognizes that its customers focused on clinical development are key to the success of this strategy, and to Illumina eventually seeing the gains from this multi-year, resource-intensive investment in future clinical expansion. The future growth of NGS will be driven in large part by the development and adoption of NGS-based clinical applications, including clinical oncology

[18] *See* Time Magazine, Illumina, Time100 Most Influential Companies (2021), *available at* https://time.com/collection/time100-companies/5953584/illumina/ (last visited August 18, 2021); Forbes, The Just 100 (2021), *available at* https://www.forbes.com/just-companies/#6bce51032bf0 (last visited August 18, 2021); Illumina in the News, *available at* http://www.support.illumina.com/content/illumina-marketing/en/company/news-center/illumina-in-the-news.html (last visited August 18, 2021).

[19] [redacted]

[20] [redacted]

applications. As discussed further below, Illumina has also vertically integrated into downstream testing applications, including NIPT and therapy selection, to expand and accelerate adoption of NGS-based clinical tests for the benefit of patients and NGS clinical test developers in those segments.

B. Formation of GRAIL

In 2015, Illumina formed GRAIL with the goal of achieving the "holy grail" in the war on cancer: a test—enabled by Illumina's sequencing technology—to detect multiple types of cancer in asymptomatic individuals through a blood draw. It was a "moonshot" ambition—as Illumina's then-CEO, Jay Flatley, put it at the time, "GRAIL is going after a much more daunting technology, scientific and biological problem that [no other company] to [Illumina's] knowledge . . . have even begun to address".[21] By forming GRAIL, Illumina hoped to "[a]ccelerat[e] development of the ctDNA cancer screening market by 10 years".[22] Thus, from the start, Illumina viewed GRAIL as an extension of its core goal of expanding and accelerating adoption of NGS technology in new applications, paving the way for NGS-based screening tests and spurring innovation.

To position GRAIL for its moonshot objective, Illumina seeded GRAIL with the talent, R&D capabilities, development plans and data it would need to investigate, through foundational, population-scale trials, how to use NGS technology for multi-cancer early detection. However, GRAIL would also require a substantial amount of capital to conduct the foundational clinical trials necessary to build the data sets for its machine learning algorithm. Given the high risks of failure at this early stage, Illumina decided to bring in outside investors to

[21] Illumina, Inc. Form 8-K, dated Jan. 10, 2016, at Ex. 1, *available at* https://www.marketwatch.com/investing/stock/ILMN/SecArticle?countryCode=US&guid=11108676&type=8.

[22] RX1914 at 7 (Python Update Slide Deck, dated Dec. 12, 2015).

spread the risk while ensuring GRAIL had the capital it needed to move from concept through clinical trials, and the freedom of a biotech startup to experiment and fail in pursuit of its "moonshot" objective. To that end, in February 2017, Illumina completed a capital raise in connection with which Illumina reduced its stake in GRAIL to less than 50%.[23]

Although Illumina reduced its investment in GRAIL in 2017, Illumina has remained heavily invested in GRAIL's success. In addition to its equity stake in GRAIL (around 12% of GRAIL's outstanding shares on a fully diluted basis before the transaction closed), Illumina has a long-term agreement to supply GRAIL with NGS instruments and reagents for its genomic testing needs, and also has the right to receive approximately [redacted] of future net sales of any GRAIL oncology products or services.[24]

C. GRAIL Today

Since 2016, GRAIL has made significant progress in developing its multi-cancer screening technology. It has demonstrated that detecting multiple cancers through a single blood draw in asymptomatic patients is possible. GRAIL is also adapting the technology platform used in its Galleri test for the development of new tests for use in other patient populations, specifically, as a minimal residual disease ("MRD") test, which will test for the recurrence of cancer in individuals who have already been treated for cancer, and a screening test in potentially symptomatic individuals to help confirm a diagnosis cancer, known as diagnostic aid to cancer ("DAC") test.

[23] Illumina, Inc. Form 8-K, dated Mar. 1, 2017, at 2, *available at* https://seekingalpha.com/filing/3436252.

[24] RX1371 at 10-11 (Amended and Restated Supply and Commercialization Agreement between Illumina, Inc. and GRAIL, Inc., dated Feb. 28, 2017), RX0847 at 1-2 (First Amendment to Amended and Restated Supply and Commercialization Agreement between Illumina, Inc. and Grail, Inc., dated Sep. 27, 2020).

After more than [redacted] million of R&D spend and more than five years of research, GRAIL launched Galleri, the first-of-its kind NGS-based multi-cancer screening test, in April 2021, as a laboratory developed test ("LDT"). Galleri is now at a critical juncture—to make the test widely available, GRAIL will have to overcome a number of significant obstacles.

Under current FDA policy, companies may launch diagnostic tests as LDTs without completing the lengthy premarket approval application ("PMA") required for FDA approval. However, a PMA is a prerequisite for reimbursement by the Centers for Medicare and Medicaid Services ("CMS"), and by most U.S. private payors. Without such coverage, GRAIL can market Galleri only to a limited set of potential customers who can afford to pay for Galleri without insurance coverage. The PMA process is difficult and time-consuming, and will be particularly challenging here as the FDA has never considered or analyzed, let alone approved, a multi-cancer screening test. [redacted]

The obstacles to obtaining widespread payor reimbursement loom even larger. GRAIL is currently hoping that proposed legislation to amend the Medicare statute will be enacted, which would allow for coverage of multi-cancer screening tests if they are FDA approved. If such legislation is not enacted, Galleri may obtain Medicare coverage only after receiving an A or B rating from the United States Preventative Services Task Force ("USPSTF"), an independent organization that makes recommendations regarding cancer screening and other clinical preventative services. [redacted] In addition to Medicare coverage, to make Galleri broadly available in the U.S., GRAIL will need to convince multiple private payors to provide reimbursement for the test. As reimbursement

expert Dr. Deverka will explain at trial, this will be a significant challenge due to the shorter-term economic modeling used by commercial payors in the U.S., and likely will require risk-sharing agreements or other innovative arrangements that reduce the risk of coverage to the payor and put more risk on GRAIL. [redacted]

Because it lacks any payor coverage, GRAIL has focused its efforts on marketing Galleri to health systems, self-funded employers and concierge medicine groups. [redacted]

[redacted]

25 [redacted]

26 [redacted]

27 [redacted]

[redacted]

28 [redacted]

29 [redacted]

30 [redacted]

31 [redacted]

[redacted]

[32] [redacted]

[33] [redacted]

In short, GRAIL today is an exciting startup that successfully developed game-changing technology, but it will need vastly more and different resources to transform into a global, sophisticated diagnostic testing company to be able to deliver the life-saving benefits of Galleri on a broad scale.

D. Proposed Re-Acquisition of GRAIL

The evidence will show that now is the optimal time for GRAIL to rejoin Illumina. The merger will enable Illumina to accelerate GRAIL's transformation from biotechnology startup to a global commercial provider of cancer screening tests. GRAIL has a much better chance of achieving broad adoption of Galleri, more quickly, as a division of Illumina than it has on its own. As summarized above, Illumina brings several unique capabilities and resources to GRAIL at this critical juncture in Galleri's development. [redacted] If the transaction is allowed to proceed, such delays can be minimized, likely resulting in an acceleration of Galleri's scaled commercialization by at least one year.

Illumina's capabilities are remarkably complementary to GRAIL given the stage of Galleri's commercialization, [redacted] Illumina is one of the few companies to achieve FDA authorization, foreign regulatory approvals and payor coverage for NGS-based tests, and also one of the few companies that has successfully manufactured and supplied diagnostic tests at scale. Illumina has spent years building the infrastructure, expertise and resources required to obtain regulatory approvals and payor coverage for its regulated products,

and to manufacture and supply them at scale under the demanding quality requirements imposed by the FDA and foreign regulators. Illumina also has significant experience running and scaling diagnostic testing services at its CLIA-certified laboratories.

Moreover, Illumina pioneered NGS, and has the world's foremost expertise in sequencing systems. NGS is relatively new as a clinical tool, and regulators, payors and healthcare providers do not have much experience with the technology, which is far more complex than other platforms used for diagnostic tests. Illumina's deep understanding of NGS is particularly important when it comes to educating regulators, payors and healthcare providers, and addressing their questions and concerns about the technology. The institutional expertise, experiences and competencies that Illumina can bring to bear to aid GRAIL in its regulatory, market access and commercialization efforts will minimize the chances of delays, and maximize the chances of accelerating Galleri's adoption at scale. Any delays in scaling Galleri will have real costs, whereas the benefits from acceleration are enormous. The evidence will show that reuniting these complementary companies to accelerate Galleri's availability to patients, and, in turn, the NGS cancer screening space, is at the core of Illumina's strategic rationale for the merger.

E. Cancer Screening

Illumina believes there is significant opportunity for NGS growth in liquid biopsy cancer screening. However, cancer screening is an unproven NGS use case as a commercial proposition, and broad adoption of NGS-based screening tests is still many years away in the optimistic case. No regulator has approved any NGS-based cancer screening test. No such tests besides Galleri have commercially launched. No cancer society has included such tests in its screening guidelines. No such tests have received approval for CMS reimbursement. And no commercial payor has announced a willingness to reimburse for the cost of such tests.

Moreover, there are a number of alternative cancer screening modalities that NGS will need to compete with to penetrate the market and become an established standard of care for cancer screening. A variety of different technologies are expected to be used for cancer screening tests in the future, including proteomics, which identifies cancer antigens or other pathologically significant proteins in blood samples, microarray, which identifies genomic mutations and methylation changes using an orderly and specific arrangement of probes attached to solid support, and PCR technology, which amplifies DNA to detect the presence of genomic mutations and methylation changes.

Complaint Counsel has identified a number of companies that it alleges are likely to launch NGS-based tests that will be close substitutes to Galleri. The evidence will show that, in reality, there is no test in development remotely like Galleri, and no basis to predict that one will emerge in the foreseeable future. As for the test developers cited by Complaint Counsel—[redacted]—not one has shown that it is likely to develop a test with attributes that would make it a close substitute for Galleri at any point in the foreseeable future.

i. [redacted]

[redacted]

[34] [redacted]

[redacted]

ii. [redacted]

[redacted]

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35 [redacted]

36 [redacted]

37 [redacted]

[redacted]

iii. [redacted]

[redacted]

38 [redacted]

39 [redacted]

40 [redacted]

41 [redacted]

42 [redacted]

43 [redacted]

[redacted]

iv. [redacted]

[redacted]

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[redacted]

v. [redacted]

[redacted]

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[redacted]

vi. [redacted]

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vii. [redacted]

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[redacted]

F. Upstream Competition

Illumina has built itself into the leading supplier of NGS products by constantly innovating and lowering sequencing costs to encourage research and development of new applications on its NGS platforms. The competitive pressure to continually innovate and drive down sequencing costs comes both from other modalities of genetic analysis for disease management (such as proteomics and PCR), and from established and emerging NGS players. As Illumina, other market participants and even the FTC have recognized, in only a matter of a few years, Illumina will face even greater competitive pressures on its NGS business. And given the potential size of the overall clinical oncology segment, and screening in particular, many of those competitors already are targeting these applications and are expected to offer competitive alternatives to Illumina in the coming years.

The evidence will show that Illumina fully anticipates a flood of upstream competition in the near future, as is reflected in Illumina's ordinary course strategy documents.[67]

[redacted]

[67] [redacted]

[redacted]

[redacted] As discussed below, this impending upstream competition is one of the key reasons why Illumina projects that, in the coming years, downstream clinical testing services will earn substantially greater margins than Illumina can earn upstream, and that, as discussed further below, sequencing costs will become a minor component of downstream profits and revenues. The documents highlighted in Complaint Counsel's Pretrial Brief underscore the stark reality; as Complaint Counsel notes, Illumina's board presentations relating to the GRAIL merger state that "clinical testing services, which would include Grail's offerings, would become the largest component of the value chain, dwarfing Illumina's own segment of instruments and core consumables."[69] As discussed further below, the only economically logical explanation for these projections is that Illumina anticipates very intense upstream competition, which will constrain its ability to charge anything close to a monopoly price—were it otherwise, Illumina (as any profit maximizing firm) would charge a monopoly price that extracts significantly more of the profits from the value chain.

As Dr. Cote will testify, it is a near-certainty that at least some of these well-funded upstream innovators will be successful launching sequencers with comparable performance and costs to Illumina's high-throughput products, making them viable substitutes and attractive alternatives for any MCED test developer.

[68] [redacted]

[69] CC Br. at 89.

i. The Sequencing Space

Illumina is currently the sequencing platform of choice for MCED test developers due to its low cost, high accuracy and high throughput. But there are multiple firms currently selling competing NGS technologies that are suitable for MCED test development. Even more companies are entering into the space with the stated expectation of competing with Illumina in the near future. The emergence of new applications for NGS technology, including liquid biopsy cancer testing, has spurred intense interest and financial support for development and growth within these competitors to Illumina's NGS technologies. For example, in the past year alone, companies have raised billions from investors in connection with NGS technologies, including the following:

- BGI raised $300 million in February 2021;[70]
- PacBio raised $900 million in February 2021 (and has since acquired Omniome);[71]
- Singular Genomics raised over $250 million in its initial public offering in May 2021;[72]
- Oxford Nanopore raised $271 million in May 2021;[73]
- Element Biosciences raised $276 million in June 2021.[74]

As summarized below, several companies have or are developing NGS platforms that are capable of achieving the necessary throughput, turnaround time, cost, and accuracy that

[70] RX3060 (Reuters, Chinese Sate Fund Invests In Gene Firm BGI, undated); RX3117 (Reuters, Chinese State Fund Invests In Gene Firm BGI, Feb. 21, 2021).

[71] RX3551 (Pacific Biosciences, Press Release, Pacific Biosciences Announces $900 Million Investment from Softbank to Support Growth Initiatives, Feb. 10, 2021).

[72] RX3638 (Singular Genomics Systems, Inc., Announces Closing of Initial Public Offering, June 1, 2021).

[73] RX3549 (Genomeweb.com, Oxford Nanopore Technologies Raises £195M, May 4, 2021).

[74] RX3185 (Element Biosciences, Press Release, Element Biosciences Closes $276 Million Series C Financing to Democratize Access to Genomics, June 29, 2021; RX3621 (The San Diego Union-Tribune, San Diego Startup Raises $276 In Bid To Rival Illumina's DNA Sequencing Supremacy, June 29, 2021).

is needed for supporting MCED tests.[75] And unlike the test developers described above, many of these companies have already begun to commercialize their products.

(1) Oxford Nanopore Technology

Oxford Nanopore Technology ("ONT") is a spin-out from the University of Oxford that launched its MinION sequencer in 2014.[76] ONT currently makes four NGS sequencers, with one more in development.[77] While ONT has historically focused on long-read sequencing, ONT has recently published research showing its capability to perform short-read sequencing. ONT's highest throughput instrument, the PromethION, has a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell.[78] The cost of sequencing on ONT platforms may actually be less than Illumina.[79]

In February 2021, researchers from Italy showed successful use of ONT's platform for profiling of lung cancer from plasma cfDNA as a reliable alternative to Illumina sequencing.[80] Accordingly, ONT's Nanopore sequencers can be successfully used now for multi-cancer screening tests, and will only gain in commercial viability and likely use for cancer screening applications in the future.[81]

[75] RX3869 ¶ 300 (Cote Report).

[76] RX3869 ¶ 293 (Cote Report).

[77] RX3869 ¶ 294 (Cote Report).

[78] RX3869 ¶ 294 (Cote Report).

[79] RX3869 ¶ 298 (Cote Report).

[80] RX3441 (Marcozzi A et al., *Accurate detection of circulating tumor DNA using nanopore consensus sequencing*, bioRxiv July 15, 2020; doi: https://doi.org/10.1101/2020.07.14.202010).

[81] RX3869 ¶ 299 (Cote Report).

(2) BGI

BGI Genomics, formerly known as Beijing Genomics Institute, is a Chinese genome sequencing company with sequencing products that are substitutes for Illumina's technology. Illumina's internal documents recognize BGI as offering an NGS instrument portfolio "that is increasingly competitive with Illumina's"[82] and "BGI is impacting ILMN business globally."[83] BGI's highest throughput instrument has a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell, as well as Illumina's proposed Lightening system, which has a projected throughput of 16 Tb per run.[84] The sequencing costs for BGI's DNBSEQ NGS sequencers are also lower than those for Illumina's NovaSeq instrument.[85] In 2019, Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China.[86]

BGI is currently enjoined from launching its sequencing instruments and related reagents in the United States, but that preliminary injunction is based on a set of patents that expire in 2023.[87]

[82] PX5027 at 059 (Illumina, Board of Directors Meeting (Virtual), Aug. 3, 2020).

[83] PX5027 at 070 (Illumina, Board of Directors Meeting (Virtual), Aug. 3, 2020).

[84] RX3869 ¶ 287 (Cote Report).

[85] RX3258 (Genengnews, MGI Delivers the $100 Genome at AGBT Conference, Feb 26, 2020).

[86] RX3498 (Natera and BGI Genomics Announce $50M Partnership to Commercialize Signatera Oncology Test in China and to Develop Reproductive Health Tests in Select Markets on BGI's DNBseq™ Technology Platform, March 11, 2019); RX3062 (BGI Genomics and Natera Announce Commercial Launch of the BGI/Natera Signatera Assay in China, June 24, 2021).

[87] RX3356 (Business Wire, Illumina Inc. Announces That U.S. Federal Court Issues Preliminary Injunction Against BGI Companies, June 16, 2020).

(3) Thermo Fisher

[redacted]

(4) GenapSys

GenapSys, Inc. launched its GenapSys Sequencer in 2019. The GenaSys Sequencer is a compact machine that sells for a list price of under $10,000,[92] yet still has performance comparable to a mid-output Illumina NextSeq 550 instrument and certain of

[88] [redacted]

[89] [redacted]

[90] [redacted]

[91] [redacted]

[92] RX3270 (GenomeWeb, GenapSys Raises $90M in Series C Round, Launches Sequencer in US).

Thermo Fisher's NGS sequencers.[93] As of 2019, Genapsys had raised over $165 million in private financing rounds to drive the commercial launch of its sequencing instrument.[94]

(5) Singular Genomics

Among other products, Singular has developed an NGS platform consisting of their G4 Instrument and associated consumable kits, which they refer to collectively as the G4 Integrated Solution or the G4 System.[95] Singular has publicly reported that it anticipates "a commercial launch of the G4 Integrated Solution by the end of 2021, with intentions for units to ship in the first half of 2022."[96]

(6)

[93] RX3869 ¶ 291 (Cote Report).

[94] RX3262 (GenapSys Raises $90M in Series C Round, Launches Sequencer in US, Nov. 20, 2019).

[95] RX3619 at 5, 6 (Singular Genomics Systems, Inc., *Form S1*, filed with the SEC on May 7, 2021 ("Singular S1")).

[96] RX3619 at 6 (Singular S1).

[97]

[98]

[99]

[redacted]

(7) Roche

Roche Diagnostics completed, in 2020, the second of two acquisitions of sequencing companies in furtherance of its stated objected of combining "electronic and biological components to sequence DNA for fast, flexible and cost-effective clinical diagnostic testing."[107] [redacted]

[100] [redacted]

[101] [redacted]

[102] [redacted]

[103] [redacted]

[104] [redacted]

[105] [redacted]

[106] [redacted]

[107] RX3613 (Roche Sequencing and Life Science, AVENIO family of NGS oncology assays, *available at* https://sequencing.roche.com/en/products-solutions/products/ngs-oncology-assays/tumor-tissue-analysis-kits/tumor-tissue-targeted-kits.html).

[redacted]

(8) Element Biosciences

[redacted]

[redacted]

108 [redacted]

109 [redacted]

110 [redacted]

111 [redacted]

112 [redacted]

113 [redacted]

114 [redacted]

[redacted]

(9) Omniome

[redacted] By early 2020, Omniome had raised over $145 million to develop this platform.[118] [redacted] In July, 2021, PacBio announced that it will acquire Omniome for $800 million, and will target early cancer screening. [redacted]

[redacted]

115 [redacted]

116 [redacted]

117 [redacted]

118 RX3532 ("Omniome closes $60 Million Series C Financing to Advance Novel Genomic Sequencing Platform," Omniome Press Release).

119 [redacted]

120 [redacted]

121 [redacted]

ARGUMENT

To prove a violation of the Clayton Act, Complaint Counsel must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Illumina and GRAIL, "at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts." *U.S. v. AT&T*, 310 F.Supp.3d 161, 194 (D.D.C. 2018). That burden is significant, especially in a case like this where Complaint Counsel's theory is speculative and the benefits of this transaction are concrete and profound: accelerating access to life-saving technology, and at lower prices. Although Section 7 requires "making a prediction about the future", and deals with probabilities, *id.* at 189-91 (D.D.C. 2018), it does not permit blocking a merger based on speculative "possibilities", *id.*, or "guesswork", and it does not permit ignoring the actual facts. *FTC v. Rag-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020) ("[A]ntitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future." (quoting *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 116-17 (D.D.C. 2004))). Complaint Counsel must therefore prove that "the challenged acquisition [is] *likely* substantially to lessen competition." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115 (D.D.C. 2004) (emphasis added); *see United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974) (alleged future harm to competition must be "sufficiently probable and imminent" to warrant relief); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1109 (N.D. Cal. 2004) (rejecting merger challenge because government failed to prove the "merger will *likely* lead to a substantial lessening of competition") (emphasis added); *see also FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1051 (8th Cir. 1999) ("Section 7 deals in probabilities not ephemeral possibilities.").

In addition, because the merger is a purely vertical one, Complaint Counsel "cannot use a short cut to establish a presumption of anticompetitive effect"; rather, it must make a "fact-specific" showing that the merger is anticompetitive. *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve."). Further, Complaint Counsel's claims must be assessed in the light of the widespread recognition that "[t]he great majority of vertical agreements are either procompetitive or have no competitive consequences whatsoever."[122] As the recently issued Vertical Merger Guidelines note, "[v]ertical mergers combine complementary economic functions and eliminate contracting frictions, and therefore have the capacity to create a range of potentially cognizable efficiencies that benefit competition and consumers."[123] As a result, Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the merger.

Moreover, Complaint Counsel cannot sustain its burden merely by showing that the merger may disadvantage some GRAIL rivals vis-à-vis GRAIL—for example, as a result of GRAIL becoming a more efficient competitor through vertical integration—since "[t]he antitrust laws . . . were enacted for the protection of competition not competitors." *Brunswick Corp. v.*

[122] PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW, AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1902(d). (5th ed. 2021).

[123] RX3701 at 11 (U.S. Department of Justice and Federal Trade Commission. Vertical Merger Guidelines, dated June 30, 2020).

Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 488 (1977). Rather, Complaint Counsel must demonstrate that GRAIL rivals would be foreclosed "in a substantial share" of a well-defined relevant product market, enabling Illumina to suppress innovation and output, and raise prices. *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 595 (1957); *see also Fruehauf Corp. v. F. T. C.,* 603 F.2d 345, 352 n.9 (2d Cir. 1979); *McWane Inc. v. FTC*, 783 F.3d 814, 838-39 (11th Cir. 2015).

Complaint Counsel invoke the burden shifting framework announced in *U.S. v. Baker Hughes Inc.*, 908 F.2d 981, 990 (D.C. Cir. 1990). Under this framework, the government bears the initial burden to "establish its prima facie case by 1) identifying the relevant product and geographic market and 2) showing that the merger is likely to 'substantially lessen competition' in that market." *U.S. v. AT & T Inc.*, 310 F. Supp. 3d 161, 191 (D.D.C. 2018), *aff'd sub nom. U.S. v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019). "If the Government satisfies its prima facie burden, the burden then shifts to defendants to 'provide sufficient evidence that the prima facie case 'inaccurately predicts the relevant transaction's probable effect on future competition.'" *Id.* Finally, if Respondents "put forward sufficient evidence to rebut plaintiffs prima facie case, 'the burden of producing additional evidence of anticompetitive effect shifts to the [government], and merges with the ultimate burden of persuasion, which remains with the [government] at all times." *Id.*

While Respondents do not dispute the applicability of the *Baker Hughes* framework to this case, Complaint Counsel improperly imports a number of concepts only applicable to horizontal mergers into this framework. *First*, Complaint Counsel argues that Respondents must prove timely, likely and sufficient entry in the upstream market, relying on case law related to the proof of entry in horizontal cases to rebut a presumption of harm shown

by the government.[124] The case law relied upon by Complaint Counsel, which is all in the horizontal context, relates to the situation where the government has made out a prima facie case of decreased concentration in the market in which the merger is occurring.[125] No case of which we are aware has applied this framework to a vertical merger challenge. It is wholly inapplicable to vertical mergers. *AT&T, Inc.*, 916 F.3d at 1032 ("But unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share."). *Second*, Complaint Counsel argues that Respondents bear the burden of showing that "ease of entry" would negate the effects of the merger.[126] Not so. Because the Open Offer is part and parcel of the proposed transaction, Complaint Counsel bears the burden of proof. Even if the burden would be on Respondents in a horizontal case, the most recent vertical challenge by the government makes clear that the initial burden of proof is on Complaint Counsel. *U.S. v. AT&T, Inc*., 916 F.3d 1029 (D.C. Cir. 2019) (noting that "the government failed to meet its burden of proof", in part, because the DOJ's expert had not considered the effect of the post-litigation offer of arbitration agreements). *Third*, Complaint Counsel asserts that Respondents bear the burden of proving procompetitive efficiencies and that those efficiencies outweigh the alleged anticompetitive effects of the transaction.[127] As explained further below, that standard arises only in horizontal transactions

[124] CC Br. at 96.

[125] *Id.*

[126] *Id.*

[127] CC Br. at 29.

where the government is entitled to a presumption of anticompetitive harm and where efficiencies are not an acknowledged portion of most transactions.

As set forth below, Complaint Counsel will be unable to satisfy its heavy burden at trial.

A. Complaint Counsel Cannot Prove its Alleged Antitrust Market

In order to establish a prima facie case, Complaint Counsel bears the burden of establishing the alleged antitrust market. *RAG-Stiftung*, 436 F. Supp. 3d at 291; *Marine Bancorp.*, 418 U.S. at 618 (defining the relevant market is a "necessary predicate" to finding a Clayton Act violation.); *see also* CC Br. at 30. "As a general rule, products constitute part of a single product market if they are 'reasonably interchangeable by consumers for the same purposes,' such that there is high cross-elasticity of demand for the products." *Xerox Corp. v. Media Scis.*, Inc., 660 F. Supp. 2d 535, 543 (S.D.N.Y. 2009) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956)). In this vertical case, Complaint Counsel's predicate burden is to establish two relevant product markets: a downstream market in which the merger is alleged to harm competition, and an upstream market in which Illumina has monopoly power to harm that downstream competition. *See* Vertical Merger Guidelines § 3 ("When the Agencies identify a potential competitive concern in a relevant market, they will also specify one or more related products.").[128] Complaint Counsel cannot meet these predicates.

Courts generally "use two approaches to help define a relevant product market", the first being the quantitative critical loss (or "SSNIP") hypothetical monopolist test prescribed

[128] Complaint Counsel argues that it "is not required to prove a related product market to prevail in a vertical merger case". CC Br. at 49. However, Complaint Counsel nevertheless purports to define a related product market.

by the Horizontal Merger Guidelines,[129] and the second weighing the "practical indicia" factors described in the Supreme Court's *Brown Shoe* decision and its progeny. *RAG-Stiftung*, 436 F. Supp. 3d at 292-93 (citing *FTC & DOJ Horizontal Merger Guidelines* (2010), § 4.1.1 and *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)). Complaint Counsel bears the burden of proof and persuasion in defining the relevant market. *See RAG-Stiftung*, 436 F. Supp. 3d at 291–92.

i. **The Downstream Market.**

Complaint Counsel alleges that the relevant market comprises all MCED tests in development; indeed, even those in mere contemplation. It appears that a test is within Complaint Counsel's alleged MCED market if it (i) uses liquid (blood-based) biopsy, (ii) can test for at least two cancers in asymptomatic patients and (iii) uses NGS technology.[130] As explained below, Complaint Counsel has failed to meet its burden with respect to the relevant market.

(1) There Is No Data to Conduct a SSNIP.

Besides Galleri, no test meeting these criteria has launched[131], and Galleri itself will not reach scale for many years.[132] Thus, as its economic expert, Dr. Scott-Morton, has acknowledged, Complaint Counsel cannot establish their alleged downstream market by "rely[ing] on data describing past purchasing patterns," or with "evidence of switching in response to price changes." Expert Report of Fiona Scott Morton ("Morton Report") ¶ 137; *see also* Morton Dep. Tr. 19:14-18; 20:9-17 (confirming she did not consider data describing the past

[129] This tests asks whether a hypothetical monopolist controlling the products in the alleged market could profitably impose at least a "small but significant and non-transitory increase in price" ("SSNIP") on at least one product in the market. *See, e.g.*, *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 121–22 (D.D.C. 2016).

[130] CC Br. at 33, 39.

[131] RX3869 at ¶ 151 (Cote Report).

[132] RX3869 at ¶ 135 (Cote Report).

purchase patterns of consumers and their responses to price changes); 20:21-21:5 (confirming she did not consider any information from buyers such as survey data); 21:18-19 (confirming she did not do a critical loss analysis). Complaint Counsel's economic expert made similar admissions when asked about the evidence she relied upon in forming her opinions. *See, e.g.*, *id*. 16:12-25 (acknowledging that "firms are still competing to create these tests" so there are no "sales data of consumers because it's too early"); 278:7-14 (admitting that today, it is "not possible" to assess the effect of a SSNIP on an MCED test "because we don't know what the subset of MCED tests are.").[133]

(2) Complaint Counsel's Use of the *Brown Shoe* Factors is Speculative and Results In A Market That Is Simultaneously Overly Broad and Overly Narrow.

In the absence of such quantitative evidence, Complaint Counsel attempts to establish its downstream market with reference to the practical indicia factors from *Brown Shoe*.[134] According to *Brown Shoe*, the boundaries of the relevant product market for antitrust purposes "may be determined by examining such practical indicia as industry or public recognition . . . , the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." 370 U.S. at 325. These indicia act as "evidentiary proxies for direct proof of substitutability." *Fed. Trade Comm'n v. Sysco Corp.*, 113 F. Supp. 3d 1, 27 (D.D.C. 2015) (citing *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.,* 792 F.2d 210, 218 (D.C. Cir. 1986)).

[133] Complaint Counsel's Brief states that Dr. Scott Morton "looks to available qualitative evidence to 'deduc[e] the degree to which a consumer would be willing to switch to an alternative product if faced with a SSNIP (or reduction in quality or availability) on an MCED test." CC Br. at 47. It is not clear how such a qualitative analysis can provide any information on a SSNIP or how it differs from the *Brown Shoe* analysis discussed below.

[134] CC Br. at 32.

The *Brown Shoe* factors referenced by Complaint Counsel do not support its speculative market. As Complaint Counsel acknowledges, the only test on the market that tests for more than one cancer is Galleri. The other tests that Complaint Counsel places in its alleged market are in early stages of development. Complaint Counsel has not identified distinctive characteristics that define the contours of a currently existing market in which Galleri competes with other MCED tests. Complaint Counsel does not present any evidence about how the purported MCED "market" actually functions or how it interacts with other types of oncology tests. (CC Br. at 31.) Nonetheless, Complaint Counsel attempts to define a relevant product market by speculating that MCED tests will have "unique characteristics" that set them apart from other tests, *id.* at 33; "distinct customers" such as primary care physicians, *id.* at 37; "distinct prices" to cover a broad population, *id.* at 38; "specialized vendors" to perform next-generation sequencing, *id.* at 39; and "industry recognition" as a "separate market", *id.* at 40. Indeed, Complaint Counsel's economic expert testified that, from her perspective, there are "a range of issues that need to be considered before you know how the substitution pattern would play out" for the various screening options available today and in the future.[135] Complaint Counsel has not adduced, and cannot adduce, the type of evidence that would be needed to support its alleged market.

In support of its analysis, Complaint Counsel relies heavily upon the self-interested predictions and future plans (for many, undocumented) of test developers while overlooking the certain differentiation of any MCED test that may be launched in the foreseeable future. For example, Complaint Counsel argues MCED tests will have different intended uses and characteristics as compared to "other non-early detection oncology tests" and will

[135] RX3852 (Scott Morton Dep.) at 47:6-19.

complement, rather than replace, existing single-cancer screening methods. *Id.* at 33-34. Complaint Counsel's economic expert, Dr. Scott Morton opines that "doctors and patients are unlikely to switch from an MCED test to one of the currently available single-cancer screening tests when faced with an SSNIP" and also "unlikely to switch from MCED tests to other types of liquid biopsy tests related to cancer, like DAC, MRD, or Therapy Selection tests, when faced with a SSNIP." Morton Report ¶ 146. But Dr. Scott Morton admits that "the nature of whether [Galleri] will be a complement or a substitute to existing technologies will depend a bit on how the test evolves," Morton Dep. Tr. 39:17-25, and will depend on other factors including "the consumer's insurance status, for example, what their insurer wants to pay for, [and] what their doctor thinks their risk is." *Id.* 40:2-15.

Complaint Counsel also ignores relevant evidence about the broader market for oncology testing. For example, conspicuously absent from Complaint Counsel's market definition argument is evidence from public and private payors. Payor reimbursement decisions with respect to MCED tests—including whether to cover MCED tests, which tests to cover and at what reimbursement level—will play a critical role in determining whether a new cancer screening test reaches the market, and lack of payor coverage will be a barrier to patient access. *See* Deverka Report ¶¶ 12-17. However, payor reimbursement decisions will take into account the clinical utility of a new MCED test and how the costs of covering the MCED test compare to the costs of the current standard of care. *Id.* ¶ 101 ("Value assessment [performed by private payors] is inherently comparative, as the goal is to inform the question, 'should we pay for this new test *compared to the standard of care*?'") (emphasis in original). For certain cancer types—cervical, breast, colorectal, and lung—the current standard of care is a single-cancer screening

test;[136] for other cancer types—the vast majority of them—there is no recommended screening and the standard of care involves diagnostic testing at a symptomatic stage of disease. Complaint Counsel ignores the fact that payor reimbursement decisions will inherently involve comparing the benefits of MCED tests with other modes of cancer detection. To achieve market access, then, MCED tests must compete with other types of cancer detection to prove they have the clinical utility required for payor coverage and reimbursement.

Underscoring its inadequacy, Complaint Counsel's alleged market is simultaneously overbroad and overly narrow. Complaint Counsel's market definition seemingly is premised not on what MCEDs are, but what they are not—they are not single-cancer screening tests, nor are they diagnostic or therapy selection tests. This definition is overbroad because it assumes, for example, that two-cancer screening tests will compete in the same market as fifty-cancer screening tests.[137] And it is over-narrow because it assumes all MCED tests will rely on NGS technology when in fact there are other technologies that can support multi-cancer screening, and because it fails to account for the likelihood that **at** least some MCED tests (included in the alleged market) will compete with other types of oncology tests (excluded from the alleged market), for example, to obtain payor coverage, a critical factor for scaled adoption.

[136] RX3866 at ¶ 13 (Serafin Decl.)

[137] [redacted]

(3) Complaint Counsel Fails to Account for Product Differentiation

Complaint Counsel compares the purported MCED tests to non-screening tests such as therapy selection tests. Of course, MCED tests have peculiar characteristics vis-à-vis tests that have completely different indications. But when compared to *each other* (or, compared to other screening modalities), which is the relevant inquiry, this comparison falls apart because each test in development that Complaint Counsel categorizes as an MCED test is highly differentiated from Galleri, and Complaint Counsel has not explained much less demonstrated that those differentiating factors are meaningless to substitution and market definition. The tests in Complaint Counsel's alleged market differ from Galleri (and for some, to a lesser extent, from each other) in a number of important ways, including:

- Number of Cancers Detected: It is undisputed that tests will differ with respect to the number of cancers they can detect. Galleri is highly differentiated in this regard as it can detect up to fifty cancer types, which no other test in development comes close to. [redacted]

- Types of Cancers Detected: It is also undisputed that tests will differ in the types of cancers they can detect. Different companies are targeting different cancer types. Some have pointed out that more specificity in a cancer test translates to less sensitivity, which may work for some cancer types better than others. [redacted]

- Cancer Signal of Origin: Galleri has the ability to identify not only the presence of cancer, but also the cancer type by detecting the cancer signal of origin. [redacted]

- Technology: GRAIL's Galleri test relies on next-generation sequencing, and some test developers [redacted] There are also other technology options available to a test developer, including IHC, FISH, PCR, microarrays, MS-based proteomics and imaging.

Complaint Counsel's market definition does not account for the "peculiar characteristics" of the different tests that it lumps together in its MCED market, despite the evident differentiation among them and in particular as compared to Galleri. *See Sysco Corp.*, 113 F. Supp. 3d 1 at 31 (citing, *inter alia*, Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 565b (4th ed. 2014) for the proposition that "substitution must be effective to hold the primary good to a price near its costs"). Complaint Counsel has not shown that a 50 cancer test with cancer signal of origin capabilities would substitute for a 10 cancer test without cancer signal of origin capabilities. Complaint Counsel has also failed to establish that the opposite is true. Given the differences in sensitivity, specificity and cancers covered by a specific test, a physician may prefer a 2-3 cancer test that tests for the specific cancers they are targeting. [redacted]

Complaint Counsel relies heavily on the fact that GRAIL names some of the test developers as competitors in its internal documents as evidence of competition. But as

[138] [redacted] *See* RX3498 (Natera, Natera and BGI Genomics Announce $50M Partnership to Commercialize Signatera Oncology Test in China and to Develop Reproductive Health Tests in Select Markets on BGI's DNBseq™ Technology Platform, March 11, 2019, *available at* https://investor.natera.com/news-releases/news-release-details/natera-and-bgi-genomicsannounce- 50m-partnership-commercialize.)

Complaint Counsel knows, GRAIL does not have access to confidential information about the state of other test developers' test. Nor does the fact that GRAIL includes a test developer in a company presentation necessarily mean that they are a competitor within the meaning of the Clayton Act.

Complaint Counsel cites *Brown Shoe* to argue that "the boundaries of the relevant market must be drawn with sufficient breadth . . . to recognize competition where, in fact, competition exists". (CC Br. at 45.) While this may be true, it is equally important not to lump in highly differentiated products in a single market where they do not compete.[139] Willig Report ¶ 11 ("The smallest set of products that pass the HMT is usually considered to be a relevant product market for the purposes of analyzing the proposed merger"); *id.* ¶ 25 ("If the plaintiff's relevant product market is too broad and overly inclusive of products, then the anticipated effects of concern are apt to be inaccurately magnified as well, and thus the balancing against procompetitive effects would be too biased to be reliable.").

ii. **The Upstream Market.**

Complaint Counsel fails to define a relevant upstream market, contending that it need not do so because, according to Complaint Counsel, the Vertical Merger Guidelines do not require that the "related market" in a vertical case be defined as a relevant antitrust product market. Complaint Counsel's position is contrary to the law: In a vertical merger, Complaint Counsel must define relevant markets for both merging parties and prove substantial market power in both upstream and downstream markets because, "[w]here substantial market power is

[139] Horizontal Merger Guidelines § 1.11 ("Specifically, the Agency will begin with each product (narrowly defined) produced or sold by each merging firm and ask what would happen if a hypothetical monopolist of that product imposed at least a "small but significant and nontransitory" increase in price, but the terms of sale of all other products remained constant."); RX3871 (Willig Report) ¶ 25 ("If the plaintiff's relevant product market is too broad and overly inclusive of products, then the anticipated effects of concern are apt to be inaccurately magnified as well, and thus the balancing against procompetitive effects would be too biased to be reliable.").

absent at any one product or distribution level, vertical integration will not have an anticompetitive effect." *Auburn News Co. v. Providence Journal Co*., 659 F.2d 273, 278 (1st Cir. 1981); *see also Comcast Cable Commc'ns, LLC v. F.C.C.*, 717 F.3d 982, 990 (D.C. Cir. 2013) (Kavanaugh, J. concurring) ("[A]bsent market power, vertical integration and vertical contracts are procompetitive. Vertical integration and vertical contracts in a competitive market encourage product innovation, lower costs for businesses, and create efficiencies—and thus reduce prices and lead to better goods and services for consumers."). Thus, it is Complaint Counsel's burden to define a relevant upstream market, yet it has not even alleged one.

Further, the "related market" asserted by Complaint Counsel, which appears to be limited to Illumina NGS technologies, is untenable. As noted above, the evidence will show intensifying competition both within the NGS space and as between NGS and other modalities, such as proteomics, PCR and microarrays. Other sequencing providers compete with Illumina's NGS systems as a platform for cancer screening tests, and, just as the downstream market is dynamic and evolving, so too is the upstream market—as the FTC itself alleged over a year ago in its challenge to Illumina's proposed acquisition of PacBio. As noted above, PacBio recently announced an agreement to acquire Omniome and its intention to develop solutions for cell-free DNA sequencing for cancer screening. Through the transaction, PacBio will acquire control of Omniome's sequencing platform, enabling PacBio to pursue applications in early-stage cancer screening and noninvasive prenatal testing. The transaction is just one example of increasing competition that Illumina faces in the upstream market for sequencing; others include the likely entry of BGI into the United States market and other innovators investing heavily in and poised to launch NGS alternatives, as described above. Particularly because these systems will be available to MCED developers well before the alleged downstream market reaches commercial

scale (and well before launch for most tests in the alleged downstream market), they must be included in the relevant upstream market. In short, Complaint Counsel has not even attempted to satisfy its burden of proving a relevant upstream product market, and its claim that Illumina has monopoly power in the "related product" market fails in light of the ample evidence of intensifying upstream competition.

B. The Proposed Transaction Will Not Harm Competition.

To make out a prima facie case, in addition to properly defining a market, Complaint Counsel must prove that a transaction is likely to substantially lessen competition in that market. As explained above, because vertical mergers are generally procompetitive, Complaint Counsel must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Illumina and GRAIL, "at this time and in this remarkably dynamic industry, [] is likely to substantially lessen competition in the manner it predicts." *U.S. v. AT&T*, 310 F.Supp.3d 161, 194 (D.D.C. 2018). That burden is significant and requires Complaint Counsel to show that the anticompetitive effects outweigh any procompetitive benefits associated with the transaction.

Complaint Counsel will be unable to establish that the merger presents the rare instance of anticompetitive vertical integration. In its Pretrial Brief, Complaint Counsel complains about the label of "speculative" that Respondents have used to describe its theory of harm, contending that the label means only "that there can be no competitive harm because MCED tests are still in development". (CC Pretrial Br. at 66.) This is a conscious mischaracterization of Respondents' position. Complaint Counsel's theory is speculative not simply because the tests it claims will be foreclosed from the merger are all in development, but because the theory depends on unsupported assumptions and cannot be reconciled with the economic evidence. Further, the theory is based on mischaracterizations of party documents and

testimony, including unfounded claims about Illumina's conduct in other areas in which Illumina is vertically integrated. And, it ignores the decidedly procompetitive impact of Illumina's only other vertical merger into a clinical diagnostic market. Moreover, reflecting the weakness of its prima facie case, Complaint Counsel relies on inapposite horizontal merger cases to argue, wrongly, that Respondents have the burden on upstream entry and the effects of the Open Offer on Illumina's ability and incentive to foreclose competition.

In the end, Complaint Counsel must show that the merger is substantially *likely* to result in Illumina having an ability and an incentive to foreclose third parties offering purported MCED tests. Complaint Counsel attempts to do so by arguing that (1) the merger gives Illumina a strong incentive to harm Galleri's alleged rivals and that (2) Illumina has the ability to harm Galleri's alleged rivals because (a) there are no alternatives to Illumina, (b) Illumina can identify and effectively discriminate against an MCED rival to Galleri and (c) Illumina has price and non-price tools to harm Galleri's alleged rivals. (CC Br. at 60–92.) Importantly, for Complaint Counsel to make out its case, *each* of these predicate factors must be present. The trial will show that Complaint Counsel cannot meet its burden to prove any of these predicates, much less all of them. As explained below, the combined firm will lack both the ability and incentive to foreclose for the following reasons: (1) there is no basis to predict any material diversion to Galleri from a hypothetical foreclosure strategy; (2) upstream competition will prevent any hypothetical foreclosure; (3) Illumina would face serious reputational costs and related damage from a hypothetical foreclosure strategy; and (4) even if it were to pursue a hypothetical foreclosure strategy, Complaint Counsel has not shown that Illumina has access to the information necessary to identify or target GRAIL's alleged rivals. To the contrary, Illumina's long history of promoting competition in markets in which it is vertically integrated cuts against

a finding that the merger is likely to harm competition. Finally, the Open Offer removes any ability Illumina would otherwise have to foreclose, effectively removing any likelihood of anticompetitive harm.

i. There is No Basis to Predict Any Material Diversion to Galleri From a Hypothetical Foreclosure Strategy.

Evaluating the effects of a vertical merger requires "assess[ing] whether the merged firm will benefit significantly from responsive changes in rivals' behavior or from their lost sales."[140] That "potential benefit depends on the extent to which any sales lost by rivals would divert to the merged firm's products in the [downstream] market."[141] Thus, Complaint Counsel bears the burden to prove that a foreclosure strategy targeting the tests it has identified as comprising the alleged MCED market would result in material diversion to Galleri. Complaint Counsel cannot make this showing.

As a matter of basic economics, the more differentiated two products are, the less likely it is that foreclosed sales from one would divert to the other. As Complaint Counsel's own expert acknowledged, if products "are sufficiently differentiate[d], then . . . the combined firm would not recapture any of those profits" and "that would be not a very successful strategy."[142] As she also acknowledged, "[t]hat's what highly differentiated means, that diversion is limited." That is the case here. As discussed above, the evidence indicates that the tests in development by GRAIL's alleged rivals will be differentiated from Galleri in several ways, including, among other things, the number and types of cancers detected, the level of sensitivity and specificity for

[140] RX2584 at 14 (U.S. Federal Trade Commission, *Commentary on Vertical Merger Enforcement*, December 2020).

[141] *Id.*

[142] RX3852 (Scott Morton Dep.) at 173:11-23.

each of the different types of cancer and the ability or inability to detect cancer signal of origin. Further, as Dr. Cote will testify, there is no evidence in the record, beyond the aspirational and unsubstantiated assertions of some Illumina customers, that there are *any* tests in development that will have attributes similar to Galleri, including number of cancers detected and the ability to detect cancer signal of origin.

Complaint Counsel's theory appears to be that any company armed with an Illumina sequencer is capable of developing a MCED test comparable to Galleri. The theory belies common sense and makes a mockery of the long and arduous path that GRAIL has traveled to develop and launch Galleri. For example, GRAIL has conducted multiple multi-year large-scale clinical studies to develop Galleri, costing several hundred million dollars, and has initiated more, aimed at demonstrating the clinical value and safety of a 50+ cancer screening test that has cancer signal of origin capabilities.[143] And while GRAIL has launched Galleri as an LDT, Galleri is still years from achieving scaled adoption, and has embarked on additional clinical studies to support those efforts. Given the low prevalence of cancer in asymptomatic average-risk individuals, such multi-year studies are essential to safely launch such a test. Moreover, it is implausible that such extensive studies could be conducted outside the public eye—or without discussion in the internal documents produced by the third parties in this action. The lack of any documented indication that these third parties have tests likely to launch in the foreseeable future with attributes like Galleri's is compelling evidence that there are none. This critical element of Complaint Counsel's case is truly pure speculation.

[143] RX3869 ¶ 138 (Cote Report); [redacted]

It is unsurprising that a cancer screening test for 50 types of cancer—which was thought to be a moonshot concept just five years ago and for which there is no precedent—is extremely challenging to develop. [redacted] Complaint Counsel's baseless speculation that test developers will develop close substitutes to Galleri in the foreseeable future does not come close to satisfying Complaint Counsel's burden.

Because Complaint Counsel cannot establish that a foreclosure strategy would be likely to result in material diversion from third-party MCED tests to Galleri, it cannot demonstrate that a foreclosure strategy would be profitable and, therefore, the merger would give Illumina an incentive to attempt it. As Complaint Counsel's economic expert acknowledged, if an Illumina customer "is no longer selling product because" it has been foreclosed, "then of course it will not be buying inputs from Illumina" and "Illumina's sequencing revenue would be lost from that rival," and foreclosure would be unprofitable unless "the tests that that rival would have sold are diverted to GRAIL." (Scott Morton Dep. Tr. 162:5-21.) Because Complaint Counsel cannot credibly demonstrate that a hypothetical foreclosure strategy by Illumina would lead to any material diversion to Galleri, it cannot satisfy its burden of proving that the merger would give rise to an incentive to foreclose any MCED test competitors. Its *prima facie* case fails on this basis alone.

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[144] [redacted]

[145] RX3869 ¶ 201 (Cote Report).

[146] RX3869 ¶ 192 (Cote Report).

ii. Upstream Competition Will Prevent Any Hypothesized Post-Merger Foreclosure.

Complaint Counsel's theory also depends on the assumption that there are *and will* be no alternatives to Illumina for MCED test development during the relevant timeframe for this case, that is, when NGS-based MCED tests are commercialized. The evidence does not support that theory. To the contrary, there is substantial evidence (*supra* at Background, F), that MCED test developers have viable alternative options to Illumina today, and will have many more within the next 1–2 years, well before any NGS-based MCED test developer reaches the point where it would be ready to commercialize an MCED test. The evidence will show that some Illumina oncology customers are likely to switch platforms *even with* Illumina competing aggressively for their business. Such switching logically would increase dramatically if (hypothetically) Illumina decreased the quality, increased the cost or withheld any NGS products or services in an ill-conceived attempt to impede the competitiveness of any of its clinical oncology customers.

Further, given that, besides Galleri, no NGS-based MCED test in development is expected to launch before [redacted] at the very earliest[147], and the overall segment is many more years out from reaching scale even in the optimistic case, any analysis of Illumina's post-merger incentives with regard to downstream rivals must take into account the dynamic nature of the upstream segment and its intensifying competitiveness. As Complaint Counsel acknowledges, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" *U.S. v. Aetna Inc.,* 240 F. Supp. 3d 1, 79 (D.D.C. 2017) (internal citation omitted). Thus, it is Complaint Counsel's burden to

[147] [redacted]

demonstrate that Illumina has the ability and incentive to foreclose during the relevant timeframe of this case. By failing to do so, Complaint Counsel paints a materially inaccurate picture of the likely future competitive landscape and Illumina's post-merger incentives, and cannot sustain its burden.

Complaint Counsel argues that these emerging NGS alternatives are not relevant to the foreclosure analysis because the future is unknown, and, according to Complaint Counsel, any one of the emerging upstream rivals could ultimately fail to develop into a strong NGS competitor for MCED test developers. Yet, as described above, there are hundreds of millions of dollars being invested to fund these NGS innovators, many of which are specifically targeting the screening (and other oncology) segments and have disclosed roadmaps that project commercial launch within the next few years—and in the case of Singular—later this year.[148] A number of these innovators are led by former Illumina executives,[149] who are extremely knowledgeable about the industry and what it takes to succeed. There is no basis to speculate that any (much less *all*, as Complaint Counsel theorizes) of these well-funded, serious players will simply fail. It is also worth noting Complaint Counsel's utterly asymmetrical approach to the evidence when it serves their interest. With regard to the alleged MCED market, Dr. Scott Morton has opined that she infers from the mere fact of "excitement" and "investment" in downstream test development that it is "highly likely that there are going to be several successful cancer tests" in the alleged MCED market. Yet in the upstream segment, the far more concrete evidence of innovation and investment in rival NGS platforms targeting the oncology segment

[148] *See* Background, 1.F.i.(5), *supra*.

[149] [redacted]

(and the impending expiration of key patents) is purportedly too "uncertain" to credit. Complaint Counsel cannot use such double standard logic to sustain its burden.

Complaint Counsel also asserts that the evidence of intensifying upstream competition can be discarded because, even if viable upstream alternatives exist or emerge, switching an MCED test to any such alternative would be too costly and time-consuming for a test developer to profitably undertake. However, Complaint Counsel—which has the burden of proof—offers no empirical support for this assertion; it has done no analysis of the size of one-time switching costs relative to the benefits of switching in a hypothetical scenario where Illumina has attempted to foreclose an MCED rival. Further, Complaint Counsel acknowledges that Illumina's oncology customers will eventually need to switch platforms to take advantage of cost reductions enabled by future Illumina high-throughput systems, [redacted][150] Yet neither Complaint Counsel nor its economic expert offers any empirical assessment of the *incremental* cost of switching from an Illumina platform to a third party platform as compared to the switching cost that would be incurred by a test developer that seeks to upgrade to Illumina's next generation system.

As Respondents' economic expert Dr. Carlton will testify, given the magnitude of the potential downstream market—which, if it reaches its full potential, could be in the tens of billions of dollars[151]—it cannot just be assumed that even high switching costs would deter test developers from migrating to a rival platform in response to a hypothetical foreclosure strategy,

[150] [redacted]

[151] [redacted]

since whether switching costs impede customer defections depends on not only the magnitude of switching costs but also the benefits from switching. Moreover, as described above, the evidence will show that customers can switch oncology test systems, and have done so. For example, Natera recently moved its commercialized MRD test to BGI.[152][153] Complaint Counsel offers no basis (and there is none) to assume that there would be materially greater barriers to switching an MCED test in development than an already commercialized MRD test. Dr. Cote, an expert on NGS technology and its usage by test developers and laboratories, will also attest to the feasibility of switching. Complaint Counsel also cannot square its claim of long-term upstream monopoly power with the reality that the cost of sequencing an MCED test on Illumina's platform is shrinking and will soon become a minor component of downstream prices and margins. At trial, Dr. Carlton will present analysis, based on normal course data from the merging parties and from Exact/Thrive (the only MCED test developer that produced detailed financial projections), showing that the cost of sequencing is expected to decline dramatically over the next few years, while margins and revenues in the downstream testing segment surge.

[redacted]

[152] *See* RX3498 ("Natera and BGI Genomics Announce $50M Partnership to Commercialize Signatera Oncology Test in China and to Develop Reproductive Health Tests in Select Markets on BGI's DNBseq™ Technology Platform," March 11, 2019, *available at* https://investor.natera.com/news-releases/news-release-details/natera-and-bgi-genomicsannounce-50m-partnership-commercialize).

[153] Complaint Counsel contends that even though BGI's technology is technically capable of supporting MCED test development—and it is undisputed that it is—"test developers" will be unwilling to use BGI because of concerns about BGI's status as a Chinese company and its ties to the Chinese government. But only one MCED test developer—by Complaint Counsel's own definition—even raised such a concern in their testimony, and others, such as Natera, clearly recognize BGI as a viable alternative.

[redacted].[154] [redacted] Turning well-established antitrust and economic principles on their head, Complaint Counsel points to the projections of Illumina's dramatically *shrinking* prices and relative future margins as proof of post-merger foreclosure, rather than what this evidence clearly signifies—that upstream competition will further intensify, providing MCED test developers with a number of alternatives to Illumina by the time they are ready to commercialize their tests, and even well before then.

For similar reasons, the notion that MCED test developers are indefinitely locked into Illumina's platform cannot plausibly be reconciled with Complaint Counsel's claim that these same companies have been investing hundreds of millions of dollars in supporting the development of MCED tests on those platforms. As Dr. Willig will explain at trial, it would be economically irrational for firms to make such large investments now if they truly anticipated

[154] RX3864 ¶ 70 (Carlton Report).

[155] RX3864 ¶¶ 70-72 (Carlton Report).

[156] [redacted]

[157] RX3852 (Scott Morton Dep.) at 167:3-6.

that they will have no options or opportunities to switch by the time their tests are commercialized and earning profits. Otherwise, these firms would be knowingly subjecting themselves to opportunistic hold-up, since (if Complaint Counsel's long-term monopoly theory had merit) Illumina would have both an incentive and ability to extract all their returns *without the GRAIL merger*.

Dr. Scott Morton has acknowledged this basic economic logic, testifying that "because this industry is nascent at the moment, [Illumina's MCED customers are] still sinking those costs", but "[a]fter the costs are sunk and the discoveries are made, then the incentive problem with raising prices is a lot reduced because those companies have invented the relevant technology."[158] Dr. Scott Morton attempts to explain away this economic evidence by claiming that, absent the merger, the market would develop into a "bilateral monopoly" where there would be only one or a few winning MCED test developers, who would then have sufficient bargaining leverage to "divid[e] the rent" with Illumina.[159] Yet she can cite no evidence to support her speculation that the market is likely to develop this way, or that the purported MCED developers she identifies have such expectations and justify their investments on this basis. Further, elsewhere, she concedes that a bilateral monopoly is unlikely, arguing that, in the but-for world without the merger, Illumina would ensure that there are multiple MCED makers in the market to "lower the profits of the MCED makers and deliver more of it to Illumina."[160] If that were true, however, then the only economically logical explanation for the sunk investments she points to is

[158] RX3852 (Scott Morton Dep.) at 171:16-24.

[159] RX3852 (Scott Morton Dep.) at 171:25-172:20.

[160] RX3852 (Scott Morton Dep.) at 290:5-291:2.

that test developers—like Illumina—anticipate intensifying upstream competition and being able to switch to alternative platforms if Illumina attempted any opportunistic hold up.

In an effort to avoid having to contend with the serious issues raised by Respondents that are outlined above, Complaint Counsel argues that Respondents bear the burden to prove that there will be entry in the upstream market in the future—rather than Complaint Counsel needing to bear its own burden. (CC Br. at 95.) Complaint Counsel cites to a number of horizontal merger cases for this proposition but appears to misunderstand the context of the cases. In horizontal merger challenges, "by putting forward statistics to show that the proposed 'merger would produce a firm controlling an undue percentage share of the relevant market, and would result in a significant increase in the concentration of firms in that market,' the Government triggers a 'presumption' that the merger will substantially lessen competition." *U.S. v. AT&T Inc.*, 310 F. Supp. 3d 161, 192 (D.D.C. 2018). The case law cited by Complaint Counsel stands for the proposition that if the merging parties wish to rebut the government's prima facie case by showing future entry in the market, then they bear the burden of doing so. *See U.S. v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 73 (D.D.C. 2011) ("Since the government has established its prima facie case, the defendants carry the burden to show that ease of expansion is sufficient "to fill the competitive void that will result if [defendants are] permitted to purchase" their acquisition target"); *F.T.C. v. H.J. Heinz Co.*, 246 F.3d 708, 717 n.13 (D.C. Cir. 2001) ("Barriers to entry are important in evaluating whether market concentration statistics accurately reflect the pre- and likely post-merger competitive picture."). In vertical cases, no such presumption exists. Instead, "[w]ith no presumption of harm in play, the Government . . . must make a 'fact-specific' showing that the effect of the proposed merger 'is likely to be anticompetitive.'" *AT&T Inc.*, 310 F. Supp. 3d at 192. Such a showing requires

proving that future entry will not prevent the combined firm from foreclosing rivals. As explained above, this is something Complaint Counsel cannot do.

iii. Complaint Counsel Ignores the Reputational Costs and Related Damage That Foreclosure Would Inflict on Illumina.

Complaint Counsel ignores the reputational and related harms that the post-merger firm likely would incur if it were to foreclose any MCED test as Complaint Counsel postulates. The vertical harm that Complaint Counsel posits will result from this merger (but which it cannot substantiate) is that Illumina will disadvantage those of its customers who are developing MCED tests, resulting in fewer and less effective MCED tests for patients.[161] Complaint Counsel further posits that firms that "have already invested hundreds of millions of dollars and years of development on their MCED tests" on Illumina's platforms will cease that development work,[162] write off those enormous sunk costs and leave their investors—which include some of the biggest names in healthcare venture capitalism and oncology—out in the cold.[163] (CC Pre-Trial Br. at 63.) Complaint Counsel does not contend, nor is it plausible, that

[161] In her rebuttal report, Dr. Scott Morton speculates that the effects of innovation competition among MCED test developers "will save significantly more lives than if competition is foreclosed by Illumina, even with a year's head start." PX6091 ¶ 86 (Scott Morton Rebuttal Report.).

[162] [redacted]

[163] [redacted]

the foreclosure scenarios it postulates would go undetected, or that Illumina could avoid the blame for them and the consequent harms. Nonetheless, Complaint Counsel claims that Illumina would not sustain any material damage to its NGS business by foreclosing MCED test developers because, according to Complaint Counsel, those developers have no choice but to use Illumina's platform for their MCED tests. Such an assessment ignores the range of obvious and severe harms that Illumina would incur by attempting foreclosure *even if* (contrary to fact) it were true that MCED tests could be viably developed and commercialized only on Illumina platforms.

Illumina has built and cultivated a reputation as a trusted supplier of NGS technology through decades of investment and partnership with laboratories, research institutions, hospitals and government entities, and by supplying cutting-edge NGS technology to anyone willing to invest in the research, development or commercialization of NGS applications to improve human health.[164] More recently, Illumina has made numerous well-publicized commitments (including via the Open Offer)—and its senior leadership will reiterate those commitments under oath at trial—that the GRAIL merger will not change Illumina's core mission nor its treatment of its clinical oncology (or any other) customers.[165] Turning its back on these commitments in the way Complaint Counsel hypothesizes—and purportedly impeding innovation that is focused on solving a devastating healthcare problem that has affected nearly every family in the world—would risk swift backlash and lasting damage to its brand and NGS

[redacted]

[164] [redacted]

[165] RX3340 (Illumina Open Offer).

business. *See AT&T*, 310 F. Supp. 3d at 241 n.51 ("Given its trial presentation, I am hard-pressed to conclude that AT&T would (much less could) retreat from the commitment in light of the apparent reputational costs of doing so").

There are a number of harms that such a strategy would invite, separate and apart from the loss of upstream sales to MCED test developers. For example, many innovators would choose not to invest in developing emerging and future applications using Illumina's platforms—not just limited to screening—opting instead to pursue such applications on rival upstream platforms, or not at all. Even Complaint Counsel's economic expert admits that test developers have viable alternatives to Illumina for development of applications outside the alleged MCED market.[166]

This in turn would stunt the growth and expansion of NGS to new applications and diminish Illumina's future sales in markets in which GRAIL is not active, making recoupment of those lost sales impossible. As Dr. Carlton will testify, an upstream firm that relies on customers continuing to innovate on its platform to generate demand for its products, including in applications that have not yet been developed or possibly even conceived (as MCED was at best a moonshot concept for NGS as recently as 5 years ago), would consider the impact of a foreclosure strategy on its reputation, which influences whether those customers continue to use its platform.[167] Yet Complaint Counsel ignores this upstream harm entirely.

Further, over the coming years, the merged firm will require the support and good will of a range of key voices in the oncology, physician, payor, and patient communities, as well as policy makers across the globe. Complaint Counsel does not offer any plausible explanation

[166] *See, e.g.*, PX6091 at ¶ 88 (Scott Morton Rebuttal Report) ("My understanding is that—in contrast to the MCED market—NIPT test providers may have upstream options other than Illumina's NGS platform").

[167] RX3864 ¶ 49 (Carlton Report).

as to why these communities, who will be important to the success of GRAIL's tests, would support the merged firm if its conduct deprived them of innovative screening tests and resulted in loss of life, as Complaint Counsel speculates.

The point is not that Illumina would engage in such tactics, or that it has the ability to cause such foreclosure—it would not and does not for the reasons discussed herein—but to highlight obvious damage that Illumina would be subjecting itself to if it acted as Complaint Counsel hypothesizes. It is implausible that Illumina would invite such harms upon itself for the speculative hope of future diversion to Galleri. And, by not accounting for such effects, Complaint Counsel presents a greatly distorted and inaccurate picture of Illumina's post-merger ability and incentives to foreclose competition in the alleged MCED market.[168]

iv. Complaint Counsel Has Not Shown that Illumina Can Identify and Effectively Discriminate Against An MCED Rival to Galleri.

Complaint Counsel's foreclosure theory relies upon the proposition that Illumina will be able to identify and specifically target rivals to Galleri. Complaint Counsel cannot show that Illumina has that capability. Although Illumina may have an understanding of the types of applications a customer is developing or marketing [redacted], in many cases it does not know what specific tests are in its customers' development pipeline. For example, many of the customers' MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close

[168] Complaint Counsel asserts that Illumina attempted to foreclose downstream rivals in other applications, specifically therapy selection and NIPT, and that reputational concerns were not a constraint to such foreclosure in those markets. But as discussed below, there is no evidence of foreclosure, much less harm to consumer welfare resulting from Illumina's vertical integration, in those applications. To the contrary, investment and innovation in those markets is thriving, as are the third-party tests that Complaint Counsel alleged Illumina foreclosed.

substitute to Galleri, or a market-expanding complement. Moreover, Illumina's instruments and consumables are multi-use products that can be and often are used by Illumina customers for a variety of sequencing applications. For example, Illumina markets its NovaSeq instrument and consumables, which are used by GRAIL for developing its early-detection tests, as "[f]lexibl[e] for virtually any genome, sequencing method, and scale of project".[169] If, hypothetically, Illumina were to cut off service to an instrument as Complaint Counsel speculates, that action could impact a range of tests (commercialized and in development), resulting in upstream losses without offsetting downstream gains from diversion. Complaint Counsel's simplistic foreclosure theory does not take these real-world constraints into account.

v. Illumina's Prior Vertical Integrations Do Not Support Complaint Counsel's Speculative Theory of Harm Here.

Complaint Counsel argues that Illumina's prior vertical integrations support its theory. (CC Br. at 92.) The opposite is true.

(1) NIPT

In arguing that Illumina will engage in foreclosure conduct if it vertically integrates, Complaint Counsel is silent on the most relevant example, Illumina's entry into the Non-Invasive Prenatal Testing or NIPT space through its vertical acquisition of Verinata Health, Inc. ("Verinata"). This acquisition is particularly instructive because, unlike the examples cited by Complaint Counsel, the NIPT space provides a direct example of what happens when Illumina enters a market through vertical acquisition. It is no wonder Complaint Counsel ignores this example. The evidence from Illumina's entry into the NIPT space is unambiguous. Rather

[169] RX2557 at 1 ("Illumina NovaSeq Applications: Broad Range of Applications—All on One Platform", www.illumina.com/systems/sequencing-platforms/novaseq/applications.html (last visited Jan. 24, 2021)).

than foreclosure, Illumina's entry brought increased competition, lower prices, increased output and enormous benefits to patients.

In February 2013, Illumina acquired Verinata which had developed an NIPT test for fetal chromosomal abnormalities using a blood sample.[170] At the time it was acquired, Verinata used Illumina sequencers to develop and perform its test, so the acquisition was vertical, just as Illumina's acquisition of GRAIL is vertical. At the time of the acquisition, Verinata was one of four companies offering an NIPT test in the U.S.: Sequenom was first to market in 2011, followed by Verinata, Ariosa, and Natera.[171] As in this case, Illumina was the upstream supplier of sequencing inputs to each of these companies. If Complaint Counsel's theory were correct, one would expect to see evidence of diminished competition following Illumina's entry. The opposite is true.

As Dr. Carlton will testify, since the acquisition, the number of NIPT tests conducted by Verinata's rivals on Illumina's platforms in the U.S. has increased in each year for which there is available data.[172] Figure 1 below shows that total NIPT tests conducted by Verinata's rivals on Illumina's sequencing platform have more than doubled between 2015 and 2019.

[170] RX3864 (Carlton Report) ¶ 163.

[171] *Id.* ¶ 164.

[172] *Id.* ¶ 165.

Figure 1: NIPT Tests Conducted in the U.S. by Verinata Rivals on Illumina's NGS Platform[173]

Dr. Carlton will also testify that, although total output has expanded, Verinata's share of U.S. NIPT sales has decreased.[174] In contrast, Natera became the market leader after Illumina acquired Verinata, with a consistently high share. Figure 2 below shows the respective shares of U.S. NIPT providers who use the Illumina NGS platform.[175]

[173] *Id.* ¶ 165 (Figure 3).

[174] *Id.* ¶ 166.

[175] *Id.* 166.

Figure 2: Shares of NIPT Tests Conducted in the U.S. on Illumina's NGS Platform[176]

Moreover, new entry into NIPT testing in the U.S. has steadily occurred, suggesting that downstream competitors are not concerned that Illumina will act anticompetitively. Figure 3 below shows the NIPT providers in the U.S. that use Illumina's platform and which providers entered or exited each year.[177] Since Illumina acquired Verinata, seven new NIPT providers have launched using the Illumina platform and two have exited (with one customer switching to a non-Illumina platform and one customer being acquired). Overall, the number of NIPT providers on Illumina's platform has more than doubled. Such entry is

[176] *Id.* ¶ 166 (Figure 4).

[177] Other providers, using other sequencing platforms, may exist.

inconsistent with the claim that Illumina has disadvantaged downstream rivals or the fear that it will in the future disadvantage downstream rivals to Verinata.

Figure 3: Number of NIPT Providers Using Illumina's Sequencing Platform[178]

(2) Therapy Selection

Complaint Counsel cites Illumina's organic entry into therapy selection as an example of Illumina Illumina purportedly engaging in foreclosure tactics in an area where it is vertically integrated. Fundamentally, Complaint Counsel has not actually examined the therapy selection market or the impact of Illumina's vertical integration in it; and it has not examined whether there has been actual foreclosure in therapy selection or a loss of consumer welfare due

[178] *Id*. ¶ 167 (Figure 5).

to Illumina having its own therapy selection test. Complaint Counsel's "analysis" of therapy selection is based only on mischaracterized anecdotal evidence. In reality, the parade of horribles and innovation harms that Complaint Counsel speculates will occur in the alleged MCED market as a result of the GRAIL merger have not materialized in the therapy selection space today, and Complaint Counsel points to no evidence to the contrary.

Today, Illumina has IVD agreements in place with Roche, PGDx and numerous other test developers in therapy selection that are formidable competitors to Illumina. Illumina provides customer support to its therapy selection rivals and there a growing amount of investment and innovation in this space. From a strategic perspective, Illumina views more test developers using its IVD platform (which it refers to as "IVD partners") as positive regardless of whether there is vertical competition.

Contrary to the record evidence, Complaint Counsel claims that, in the therapy selection space, Illumina has "denied IVD rights or charges substantial fees to certain customers in order to protect its own competitive position" (CC Br. at 82), Dr. Scott Morton cites two purported examples of prior behavior that she claims illustrate Illumina's intent to foreclose MCED test developers. [redacted][180]

[179] *Id.* at ¶ 193. Therapy selection tests are used to predict which existing treatments (typically drug therapies) are suitable for treating a particular patient's cancer. As a result, therapy selection test developers compete with each other to convince pharmaceutical companies—who market the therapies—to partner with them for a particular therapy.

[180] PX6090 at ¶ 211 (Scott Morton Report).

[redacted]

[redacted][181]

[redacted]

[181] *See* RX0383 ("First Amendment to IVD Test Kit Development Agreement"). [redacted]

[182] *See, e.g.*, PX6090 at ¶¶ 212–214 (Scott Morton Report).

[redacted]

[183] [redacted]

[184] Further, some at Illumina were initially wary of partnering with Roche given that Roche had attempted a hostile takeover of Illumina years earlier.

[185] Complaint Counsel also fails to assess whether the fact that Roche attempted a hostile takeover of Illumina in 2012 may have made Illumina reticent to work with Roche.

Finally, as discussed below, Illumina has committed to provide IVD rights in the cancer screening space on terms that are consistent with prior agreements. Thus, any alleged delay or reticence to provide such rights in other markets is simply irrelevant.

(3) GRAIL Formation and Spinout

Complaint Counsel points to Illumina's early relationship with GRAIL as an example of Illumina's incentives when it was integrated with GRAIL. (CC Br. at 92.) Specifically, Complaint Counsel points to special pricing and other benefits provided to GRAIL when it was originally formed. (*Id.*) But these examples are simply not relevant to the current acquisition. At the time of GRAIL's formation, the objective of creating a cancer screening test was still a moonshot objective and Illumina believed that without special pricing, it would be impossible to develop a cancer screening test.[186] These same considerations no longer exist for many reasons, including because (1) the pricing of sequencing has gone down since 2016; and (2) Illumina's assumptions about the volume of sequencing required to develop a cancer screening test were significantly higher than what is actually required. In any event, GRAIL's test is now already available. Moreover, as discussed below, Illumina has committed through its Open Offer to provide the same pricing terms to all cancer screening test developers. Complaint Counsel fails to explain how this is consistent with its theory.

vi. Complaint Counsel Fails to Properly Account for Illumina's Open Offer.

Complaint Counsel asserts that the Open Offer is a remedy to an anticompetitive merger and that, accordingly, it is Respondents' burden to prove that the remedy will preserve competition in the alleged relevant market. Complaint Counsel has it backwards. The Open Offer is not a remedy; it is an irrevocable offer of a supply agreement (and IVD agreements), the

[186] RX3815 (Naclerio (Illumina) Dep.) at 275:14-276:4.

framework of which is substantially similar to the supply (and IVD) agreements that Illumina enters into in the normal course with numerous customers. Illumina's normal course contracts are real-world facts that impact Illumina's incentives and constrain its conduct, and so too is the Open Offer. As such, Complaint Counsel must account for the effects of the Open Offer, just as it must account for all relevant economic facts in its attempt to demonstrate that foreclosure effects are likely as its prima facie burden demands. *See Arch Coal*, 329 F. Supp. 2d at 159 (citing defendants' post-merger transaction commitment in rejecting claim of harm). This is especially true in a vertical merger where the government is required to make a fact specific showing of anticompetitive harm. *See U.S. v. AT&T, Inc.,* 916 F.3d 1029, 1046-47 (D.C. Cir. 2019) (noting that "the government failed to meet its burden of proof" because DOJ's expert had not considered effect of post-litigation offer of arbitration agreements). Complaint Counsel's failure to do so alone provides a basis to reject Complaint Counsel's woefully incomplete and speculative theory of post-merger incentives and vertical harm.

Complaint Counsel argues that Illumina will use the following tools to foreclose GRAIL's rivals: (1) increasing prices; (2) impacting supply; (3) diminishing service and support; (4) delaying or denying access to new technology; and (5) denying access to information and agreements for FDA approvals.[187] As Respondents will show at trial, the Open Offer effectively prevents Illumina from engaging in all of the conduct that Complaint Counsel enumerates in its brief. Specifically, the Open Offer guarantees that:

Pricing

- Under a 12-year supply agreement, Illumina will not increase the price of any of the supplied sequencing instruments or consumables;

[187] (CC Br. at 72-85.)

- Far from increasing the price, by 2025, Illumina will decrease the cost of sequencing on Illumina's highest throughput sequencing instrument, using the highest throughput consumable, by at least 43%, for all customers, regardless of application or use case;

- All customers shall receive "universal pricing" for any new sequencing product, and customers shall receive access to the same sequencing products at the same pricing as GRAIL under a "most-favored nations" clause;

Access to Continued Supply & Services

- During that 12-year term, customers will have uninterrupted supply of the sequencing instruments and consumables that they use, and associated services;

- To the extent there is any supply shortage, Illumina shall not favor GRAIL in allocating any remaining supply of sequencing instruments and consumables;

- Illumina will not discontinue any sequencing product supplied for a 12-year term as long as any given customer continues to purchase that product;

Access to Information and Agreements for FDA Approvals

- Illumina will provide any documentation or information reasonably required to seek FDA approval or FDA marketing authorization to sell a clinical test using the sequencing products supplied under the agreement;

- Any customer who wants to develop an in vitro diagnostic ("IVD") distributable kitted test using Illumina's FDA-regulated ("Dx") systems may enter into a separate agreement with Illumina under any one of three standard contracts;

In addition, the Open Offer provides additional protections, including audit and arbitration provisions, to customers that are separate and apart from the foreclosure concerns that Complaint Counsel has raised, including:

- To the extent Illumina receives confidential information from any customer, Illumina will not share that information with GRAIL;

- An annual audit will be conducted by an independent third-party auditor confirming compliance with the terms of the supply commitments, and

Illumina shall have ongoing obligations to provide information to the third party auditor to comply with that annual audit obligation;

- Customer can call for an additional independent third-party audit at any time, provided they have a good faith basis to do so; and
- Disputes on supply terms will be adjudicated through baseball-style arbitration, and Illumina must continue to supply products to the customer during the pendency of any such dispute.[188]

Complaint Counsel has failed to meet their burden to how why the Open Offer would not resolve any ability of Illumina to foreclose GRAIL's rivals.

There is no urgency to sign the Open Offer because even after Illumina and GRAIL become fully integrated, customers have six years to accept it.[189] [redacted][190] [redacted]}[191]

Complaint Counsel's criticisms of the Open Offer are based entirely on assertions by certain Illumina customers whose representatives testified that they view the Open Offer as insufficient to prevent them from being disadvantaged post-merger. (CC Br. at 112-120.) Cross-examination of these customers' representatives, and other trial evidence, will reveal that these

[188] RX3340 (Open Offer).

[189] RX3340 at 1 (Open Offer).

[190] {[redacted]

[191] [redacted]

purported concerns are based on unfounded speculation about theoretical ways Illumina could circumvent the Open Offer that are not realistic and are fully addressed by the Open Offer's audit and arbitration provisions. The trial evidence will also show that these witnesses, and their purported concerns, simply are not credible; in negotiations with Illumina, they have made patently unreasonable demands that are unrelated to any viable foreclosure concern, [redacted] and extremely low prices that they would never receive absent the transaction. They have made these demands despite stating in deposition testimony that they [redacted] or that they feel that they have freedom to operate based on their own patent portfolio. And at the same time, those same customers have expressed interest in the terms of the Open Offer, and many of these test developers have continued to negotiate with Illumina about incorporating the Open Offer into their own supply agreements.[192] The negotiating positions of these third parties do not reflect good-faith concerns about future foreclosure, but an opportunistic desire to gain a business advantage.

Complaint Counsel also fails to account for the strong signal that the Open Offer sends about Illumina's actual incentives. Similar to the arbitration offer in *AT&T*, the Open Offer "will have real world-effects" and puts the merging parties' "'money where [their] mouth is' in showing that the proposed merger, far from being aimed at 'doing any of the things that the government alleges,' is instead a 'vision deal' being pursued to achieve 'lower prices, improved quality, enhanced service, and new products.'" *AT&T*, 310 F. Supp. 3d at 241 n.51.

[192] [redacted]

vii. Complaint Counsel Has Not Shown That Tactics Available To Illumina After the Open Offer Would Foreclose GRAIL's Rivals.

As explained above (Sections B.i-vi), the merger will not give Illumina either the incentive or the ability to foreclose GRAIL's alleged rivals. But even if it did, the Open Offer effectively prevents the combined firm from doing any of the things that the FTC alleges will happen, and the penalties for violations affect Illumina's incentives to even attempt such acts. For example, the Open Offer explicitly prevents Illumina from raising prices or stopping supply of sequencing instruments.[193] Complaint Counsel is left to argue that Illumina will use loopholes to effectively get around the terms of the Open Offer, such as providing GRAIL's purported rivals with less experienced technicians. Scott Morton at ¶ 311. But Complaint Counsel offers no credible evidence that Illumina is capable of engaging in such conduct, particularly given the robust audit and arbitration provisions of the Open Offer. Moreover, Complaint Counsel has also not quantified the harm that would be caused by such conduct, much less shown that it would rise to the level of market foreclosure.[194] Accordingly, any such arguments necessarily fail to meet the government's heavy burden.

C. The Transaction Will Generate Procompetitive Efficiencies that More than Offset the Alleged Harm

As explained above, to prove a violation of the Clayton Act, Complaint Counsel bears the ultimate burden to make a fact-specific showing that "notwithstanding the merger's [] procompetitive effects" the transaction is likely to "substantially lessen competition in the manner it predicts". *U.S. v. AT&T*, 310 F. Supp. 3d 161, 194 (D.D.C. 2018).

[193] RX3340 at 1 (Open Offer).

[194] [redacted]

Unlike horizontal transactions, it is widely recognized in government guidance, economic literature and caselaw that vertical transactions can have significant efficiencies:

- "Vertical mergers combine complementary economic functions and eliminate contracting frictions, and therefore have the capacity to create a range of potentially cognizable efficiencies that benefit competition and consumers. Vertical mergers combine complementary assets, including those used at different levels in the supply chain, to make a final product. A single firm able to coordinate how these assets are used may be able to streamline production, inventory management, or distribution. It may also be able to create innovative products in ways that would not likely be achieved through arm's-length contracts. . . The Agencies do not challenge a merger if cognizable efficiencies are of a character and magnitude such that the merger is unlikely to be anticompetitive in any relevant market."[195]

- "Economists have conducted a number of retrospective studies of vertical mergers. Most suggest that consumers benefit. For example, LaFontaine and Slade found in a 2007 survey that "efficiency considerations overwhelm anticompetitive motives in most contexts." A 2005 survey by four FTC economists found similar results. So did a 2018 survey by economists at the Global Antitrust Institute."[196]

- "Because many vertical mergers create vertical integration efficiencies between purchasers and sellers, many if not most vertical mergers are either procompetitive or competitively neutral. Potential efficiency benefits involve improved coordination in pricing, production, and design that can reduce costs and improve product quality. They also involve more efficient input usage and promotion."[197]

- "Vertical mergers may cut sales and distribution costs, facilitate the flow of information between levels of the industry . . . [,] create economies of scale in management, and so on."[198]

- There is "recognition among academics, courts, and antitrust enforcement authorities alike that "many vertical mergers create vertical integration efficiencies between purchasers and sellers."[199]

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[195] RX3701 at 11 (U.S. Department of Justice and Federal Trade Commission. Vertical Merger Guidelines).

[196] Christine Wilson, *Reflections on the 2020 Draft Vertical Merger Guidelines and Comments from Stakeholders*, *Remarks at the DOJ Workshop on Draft Vertical Mergers* (March 11, 2020).

[197] Michael H. Riordan & Steven C. Salop, *Evaluating Vertical Mergers: A Post-Chicago Approach*, 63 Antitrust L.J. 513, 519 (1995).

[198] Robert H. Bork, *The Antitrust Paradox* 227 (2d ed. 1993).

[199] *U.S. v. AT&T Inc.*, 310 F. Supp. 3d 161, 193 (D.D.C. 2018), *aff'd sub nom. U.S. v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019).

Accordingly, the government bears the initial burden to demonstrate that a vertical merger is anticompetitive when balancing any alleged harm against any procompetitive efficiencies. In the only vertical merger challenged brought by the Department of Justice in over four decades, the District Court of the District of Columbia applied this approach. *U.S. v. AT&T Inc.*, 310 F. Supp. 3d at 195 ("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."). In fact, even the government's expert in that case conceded that such balancing was necessary. *Id.*at 193 ("[A]ny proper assessment of a proposed merger, Professor Shapiro testified, must consider both the positive and negative 'impact[s] on consumers' by 'balancing' the proconsumer, 'positive elements' of the merger against the asserted anticompetitive harms."). And a sitting FTC Commissioner has also advocated for a similar approach.[200]

Complaint Counsel attempts to turn the burden on its head by pointing to inapposite language from the Horizontal Merger Guidelines and horizontal merger cases to suggest that Respondents bear the burden of proof to show that efficiencies exist and outweigh alleged anticompetitive effects. (CC Br. at 105–106.) But these authorities are not applicable to a vertical merger where efficiencies are widely acknowledged to exist.[201]

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[200] Christine Wilson, *Reflections on the 2020 Draft Vertical Merger Guidelines and Comments from Stakeholders*, *Remarks at the DOJ Workshop on Draft Vertical Mergers* (March 11, 2020) (noting that "for any effects analysis" involving efficiencies "merging parties have a burden of production, but the Agencies bear the burden of proof").

[201] Complaint Counsel states that the Court in *AT&T* "rejected 'as a matter of law and logic', defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the government must "account for all defendants' proffered efficiencies as part of making its prima facie case". (CC Br.

Moreover, regardless of who bears the initial burden on merger-specific with regard to efficiencies, the case law is clear that such efficiencies need not be "capable of precise quantification," *Arch Coal*, 329 F. Supp. 2d at 153, but rather must be based on "credible evidence" of "a prediction backed by sound business judgment." *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1089-90 (D.D.C. 1997). As discussed below, regardless of the exact nature of the legal burden, Respondents will present sufficient evidence at trial showing that the efficiencies stemming from the transaction exist and outweigh any alleged anticompetitive effects.

Complaint Counsel also attempts to hold Respondents to an impossibly high standard to show that the procompetitive effects are merger-specific, only acknowledging an efficiency if it could never be achieved by any other means. Case law is clear that Respondents are not required to show that claimed efficiencies are impossible to achieve except through the challenged merger. Rather, the "real question is whether the alternatives to merger are practical and more than merely theoretical." *U.S. v. Anthem, Inc.,* 855 F.3d 345, 357 (D.C. Cir. 2017) (citing DOJ & FTC, *Horizontal Merger Guidelines* § 10 (2010)). Even the "DOJ and FTC consider only alternatives that are practical in the business situation faced by the merging firms" and "do not insist upon a less restrictive alternative that is merely theoretical." *Id.* at 211. Thus, the relevant question is not whether Complaint Counsel's experts can imagine that Grail could achieve some of the benefits Illumina will deliver to GRAIL through the merger theoretically could be achieved by GRAIL's merger with another established clinical diagnostic company, but rather whether those benefits could be achieved by the practical options facing GRAIL absent the

at 27.) However, the language Complaint counsel points too is merely dicta as the Court found that the government had failed to meet their initial burden. Moreover, because the Court credited efficiencies that the government acknowledged in its analysis, the dicta at most stands for the proposition that Respondents bear the burden of production with regard to procompetitive efficiencies. The burden is still on Complaint Counsel to show that any proven efficiencies do not outweigh alleged anticompetitive effects.

merger. The evidence will show that none of GRAIL's alternative options, including an IPO, would have been able to achieve the enormous procompetitive efficiencies associated with the transaction.

i. The Procompetitive Benefits of the Transaction Are Enormous.

Respondents will show at trial that the transaction will lead to enormous procompetitive benefits that far outweigh any harm alleged by Complaint Counsel. *First*, the transaction will accelerate Galleri's widespread adoption by accelerating the timeline to obtain FDA approval and payor coverage, and the international expansion of GRAIL's tests. These efficiencies will accelerate Galleri's widespread adoption by at least one year and save between 7,000 and 10,000 lives over a nine-year period. Respondents will show that the value of this acceleration is conservatively estimated at $37 billion over a nine year period.[202] *Second*, the transaction will lead to significant R&D efficiencies which have the potential to lead to new discoveries that will improve the lives of patients and consumers.[203] While the monetary impact of these efficiencies is not currently calculable, it is potentially enormous. *Third*, the transaction will lead to significant, cognizable cost savings including through the elimination of double marginalization, EDM, which is often a feature of vertical mergers, elimination of inefficient pricing caused by royalties and variable cost savings from supply chain efficiencies and lab operation efficiencies.[204] As explained below, these potential benefits are merger specific and far outweigh any alleged anticompetitive effects alleged by Complaint Counsel.

[202] RX3864 (Carlton) ¶¶ 117–123.

[203] RX3864 at -84, ¶¶ 127–129 (Carlton Report).

[204] RX3864 at -67-74, ¶¶ 101–111 (Carlton Report).

ii. The Transaction Will Accelerate The Adoption of Galleri.

Respondents will show that the proposed transaction will allow Illumina to accelerate the broad commercialization of Galleri by at least one year.[205] For Galleri to be widely available it will require FDA approval, coverage by private and public payors and the ability to scale manufacturing, delivery and use of the test to millions and patients while GRAIL has been able to operationalize its Galleri test, GRAIL will need to develop significant resources to broadly commercialize its product. Illumina has already developed these resources through its own commercialization of NGS-based clinical tests and will be able to leverage its significant resources, capabilities and experience to accelerate access to and adoption of Galleri.[206] Accelerating the commercialization of Galleri not only gives that more individuals will have access to a potentially life-saving test earlier, but because Galleri works, also Respondents anticipate that this increased access will directly translate into thousands of lives saved.[207]

Complaint Counsel argues that Respondents' acceleration benefits are neither verifiable nor merger specific. As explained below, however, Complaint Counsel's arguments ignore evidence of GRAIL's current challenges and Illumina's demonstrated capabilities in FDA approvals, payor coverage and international expansion that are verifiable. While Complaint Counsel seeks to impose an arbitrary requirement that any anticipated acceleration has been calculated in deal documents to be substantiated, Respondents will show that its anticipated acceleration by at least one year is a conservative calculation that will be substantiated with

[205] PX2613 at 002 (Presentation: Appendix A – Illumina/GRAIL Efficiency Analysis).

[206] [redacted]

[207] PX2613 at 002 (Presentation: Appendix A – Illumina/GRAIL Efficiency Analysis).

evidence and expert testimony.[208] The expected acceleration of Galleri's commercialization is also merger specific because GRAIL could not replicate Illumina's capabilities and experience could not be replicated by GRAIL absent the transaction within the same time period, and Complaint Counsel only offers hypothetical scenarios with no evidence to suggest otherwise.

(1) Acceleration of FDA Approval

Achieving FDA regulatory approval of Galleri—a completely novel technology never before reviewed by the agency— is a daunting challenge for GRAIL. Novel genomic-based multi-cancer tests relying on methylation patterns and machine learning presents a unique challenge for regulators, whose only experience has been to approve cancer detection tests one cancer at a time. As an in vitro diagnostic ("IVD") test for cancer, Galleri will require premarket approval ("PMA")—the "most stringent type of device application required by the FDA".[209] Given the burdensome requirements of the PMA application and the need for extensive clinical evidence demonstrating validity, it often takes companies years to prepare complete PMA applications.[210]

[208] [redacted]

[209] *See* RX3866 (Serafin Decl.) ¶¶ 28-30. In order to establish that its Galleri test is safe and effective, GRAIL will need to prepare and submit a PMA application, including a complete description of the methods used in, and the facilities and controls used for all aspects of the Galleri test. *Id.* at ¶ 30 (requiring that the PMA application include a description of all manufacturing, processing, packing, storage and where appropriate, installation of the device.) A PMA application must also demonstrate and describe a quality system that will meet the FDA's rigorous requirements to ensure safety of medical devices. *Id.* at ¶ 31; Exhibit 4 (outlining the additional Quality System requirements for a PMA compared to an LDT).

[210] RX3899 (Serafin Decl.) ¶ 32.

[redacted] Complaint Counsel ignores these challenges (without support or relevant expert analysis) when it suggests that GRAIL could "likely accomplish" the same acceleration Illumina will provide absent the proposed transaction. (CC Br. At 106.)

Illumina brings significant regulatory experience and a large regulatory team with a deep knowledge of the FDA's rigorous requirements. With 23 employees devoted to Illumina's regulatory capabilities, Illumina's team [redacted]

[211] *See* RX0582 at 2 (Presubmission Discussions between GRAILL and FDA re Galleri) (the FDA informed GRAIL that its STRIVE study was insufficient because GRAIL cannot "directly confirm the results of [its] test nor will [GRAIL] assess how the test results impacted patient treatment decisions" and because the STRIVE study was not sufficiently representative of the intended use population).

[212] [redacted]

[redacted], Illumina has previously received a PMA for an NGS-based oncology test, and has received FDA clearances on two of its sequencers, a range of reagents and other NGS-based clinical tests.[214] Most relevant, Illumina has experience in working with the FDA to approve novel NGS-based technologies for the first time, where evidence requirements and a roadmap was not established.

Complaint Counsel attempts to undercut this experience by arguing that Illumina's prior regulatory experience would not be relevant because Illumina has not previously sought regulatory approval for an MCED. (CC Br at 106.) This argument ignores that Illumina's experience is based in a deep knowledge of NGS and NGS-based tests, as well as nearly a decade of interactions with the FDA seeking approval or clearance of novel technologies.[215] Illumina has since built on its relationship with the FDA and its experience-based knowledge of the FDA's requirements for later approvals, including two PMA applications it is currently developing for its noninvasive prenatal testing ("NIPT") product and its TruSight Oncology Comprehensive ("TSO Comp") assay, an IVD test using NGS to detect variants in 523 genes in tissue samples from cancer patients.[216] Both are complicated products requiring

[213] [redacted]

[214] *See* RX3866 (Serafin Decl.) at ¶ 47; FDA Filings for Illumina Inc., *available at* https://fda.report/Company/Illumina-Inc (identifying a list of 40 FDA submissions by Illumina).

[215] Illumina was the first company to receive regulatory clearance for an NGS sequencing platform with its MiSeqDx platform in 2013. Illumina, "MiSeqDx Overview", *available at* https://www.illumina.com/systems/sequencing-platforms/miseqdx.html; FDA..report, Through achieving this clearance, Illumina worked to educate the FDA about how NGS technology works and worked to develop with the FDA to develop the framework for how the FDA evaluates NGS-based products.

[216] RX3866 (Serafin Decl.) ¶ 47.

significant interaction with the FDA. To ignore this experience because it was not specifically for the approval of an MCED is to suggest—without support—that prior FDA experience with related technologies is equivalent to having no FDA experience at all. That cannot be true.

[redacted][217] As for Complaint Counsel's opinion that Illumina has "struggled with foreseeable difficulties pursuing regulatory approval",[218] Respondents will show that the evidence on which Complaint Counsel's expert relies is not evidence of a lack of experience but rather an example of the difficulty in seeking complicated approvals on novel products—which is exactly the sort of experience GRAIL will need for its approval of Galleri.

Complaint Counsel also ignores that the resources and capabilities Illumina brings to bear are not limited to the past experience of its regulatory team. Illumina brings already approved templates for PMA applications, key software systems, and an already operationalized quality management system ("QMS")—all of which will accelerate the time required to prepare the Galleri PMA application.[219] As a smaller, start-up company, GRAIL lacks these capabilities and would have to develop these systems and capabilities from scratch, which would draw key resources and time away from other projects and other commercialization efforts. Illumina also

[217] [redacted]

[218] CC Br. at 108.

[219] RX3866 (Serafin Decl. ¶ 46) (identifying Illumina's "experienced quality organization and robust QMS" to address FDA requirements).

brings cross-functional capabilities beyond its regulatory team, including experienced resources in medical and clinical affairs and laboratory operations that will be able to provide critical support for the ongoing and future clinical studies required for PMA approval.[220] Complaint Counsel makes no argument that such resources would not accelerate FDA approvals.

Complaint Counsel argues that the expertise Illumina offers could be provided by another potential acquirer. But such a hypothetical acquisition would be relevant here only if it were shown to be a practical, rather than a theoretical, alternative. Complaint Counsel has not demonstrated that an acquirer with the equivalent of Illumina's expertise was or is available.

Complaint Counsel further argues that the expertise Illumina offers is not merger-specific, because its expert opines that GRAIL could hypothetically achieve FDA approval through hiring additional staff or through consultants. (CC Br. at 106-07.) Complaint Counsel again ignores the evidence. As Respondents will demonstrate, Illumina's regulatory expertise is extensive and specifically tied to NGS-based clinical applications. This is not "generalized" experience that GRAIL can readily find through hiring potential new employees or consultants.[221] [redacted]

[220] RX3866 (Serafin Decl. at ¶ 45).

[221] Complaint Counsel cites only to their experts' reports which merely identify that consultants with FDA experience exist and that GRAIL intends to hire additional regulatory team members—not that GRAIL believes it will be able to achieve the same levels of expertise that it can gain through the proposed transaction. *See, e.g.*, PX6093 (Navathe Report) ¶ 24 (listing regulatory consultant firms—none of which Complaint Counsel has identified as consultants retained by GRAIL). Complaint Counsel's expert Dr. Rothman only cites to the fact that GRAIL had previously hired Illumina employees, which undercuts Complaint Counsel's argument that GRAIL will be able to find the necessary expertise outside of Illumina. *See* PX6092 (Navathe Report) ¶ 70.

[redacted][222] Respondents will show these are not capabilities that can or should be readily outsourced.[223]

(2) Acceleration of Payor Coverage and Market Access

Both Complaint Counsel and Respondents recognize the receiving coverage from private and public payors, such as Medicare, will be critical to ensuring broad access to Galleri.[224] [redacted].[225] While the FDA will require clinical trial evidence to demonstrate the clinical validity of the test (*i.e.*, that the test safely tests for the cancers its says it can test), payors require evidence not only of clinical validity but also of clinical utility (*i.e.*, the benefit to patients and payors of using the test). [redacted][226]

Respondents will demonstrate that based on a comparison of Illumina's and GRAIL's capabilities, [redacted]

[222] [redacted]

[223] RX3858 (Serafin Dep. at 122:3-125:21) (testifying that "there are only so [sic] many consultants that you could, one, identify and hire/contract right away" that could fill the roles GRAIL needs and explaining that there are several challenges where a company's regulatory experience is built largely off consultants who "when they left, they took their knowledge with them" and left a company that was unable to sustain its regulatory processes).

[224] PX6090 (Scott Morton Report) ¶ 57 ("Obtaining reimbursement coverage could allow MCED test developers to reach a larger customer base by providing access to patients who otherwise could not afford to pay for the test"); RX3867 (Deverka Report) ¶ 9 (identifying "[o]btaining coverage by private insurers and by Medicare will be key obstacles for GRAIL to overcome in order to commercialize Galleri broadly").

[225] RX3867 (Deverka Report) ¶ 10 (explaining that "[t]o inform payor decision-making, cancer screening test developers must provide robust evidence of how use of the test affects clinician decision-making and patient outcomes (clinical utility) . . .[including] concerns regarding the harms of false positives, lead-time bias, and overdiagnosis.").

[226] [redacted]

[redacted][227]

As Respondents' expert, Dr. Deverka, will testify identifies, Illumina's demonstrated capabilities, including its "strong team of dedicated staff, extensive experience with public and private payors, longstanding relationships with health systems in the United States and internationally, and its ability to enter innovative risk sharing partnerships that mitigate the financial exposure of payors that agree to offer Galleri to their insured population", are key benefits that Illumina could immediately provide post-transaction to accelerate payor coverage of Galleri.[228]

Complaint Counsel responds to only one of the many capabilities and strengths Dr. Deverka identified—Illumina's track record of being able to negotiate and complete risk-sharing agreements for evidence generation—to argue that Respondents' anticipated acceleration is not verifiable or merger specific. (CC Br. 107.) [redacted][229]

227 [redacted]

228 [redacted]

229 [redacted]

[redacted]

[redacted] [231]

[redacted]

230 [redacted]

231 [redacted]

232 [redacted]

233 [redacted]

[redacted]

Moreover, Illumina's ability to accelerate payor approval and evidence generation is not limited to its experience with risk-sharing agreements. [redacted]

[redacted]

[234] [redacted]

[235] [redacted]

[236] [redacted]

[237] RX3867 (Deverka Report) at -80, Table 6-2, (identifying examples of Illumina's Evidence Generation Projects).

[238] RX3867 (Deverka Report) ¶ 135.

[redacted] Respondents will further show that Illumina's capabilities in other areas, including its dedicated cross-functional staff, its experience with private and public payors, its regulatory experience and its global presence, and its resources will contribute to Illumina's ability to accelerate payor coverage and reimbursement for Galleri as compared to GRAIL's ability to do so alone.[239]

To the extent Complaint Counsel argues that Respondents' acceleration benefits are not merger specific because GRAIL could hire consultants to achieve the same benefits, it resorts again to speculation. As Dr. Deverka will explain, "[c]onsultants would be unable to replicate Illumina's longstanding relationships with stakeholders and its successful track record with NGS test implementation programs and risk-sharing partnerships that generate necessary clinical evidence for payors."[240] Consultants may supplement market access expertise and implement specific projects or tactics, but they are unlikely to build credible, long-term relationships with payors that will be required to bring a novel test like Galleri to market.[241]

[redacted][242] Complain Counsel's notion that

[239] RX3867 (Deverka Report) ¶¶ 118, 120.

[240] RX3867 (Deverka Report) ¶ 145.

[241] RX3867 (Deverka Report) at ¶ 145.

[242] [redacted]

Illumina and GRAIL could enter into a contractual relationship whereby Illumina would provide market access support outside of the proposed transaction is purely hypothetical unsupported.[243]

(3) International Acceleration

Respondents will also show (and Complaint Counsel does not dispute) that Illumina will provide significant international resources that will accelerate Galleri's use and adoption in the United States as well as abroad. Illumina has an international presence with platforms and/or tests registered in over 45 countries around the world.[244] Illumina has significant experience working with foreign regulators and payors and with obtaining regulatory approvals. Illumina also has teams to support its global efforts with regulatory and quality personnel in China, Japan, Korea, Singapore, Europe and Australia.[245] By contrast, GRAIL has no presence outside of the United States and the United Kingdom.[246] [redacted] Through the proposed transaction, Illumina will be able to dramatically increase GRAIL's ability to access international markets and to achieve regulatory and payor approvals outside the United States. In turn, this international acceleration will allow Galleri to gather data from more patients in less time and

[243] Neither GRAIL nor Illumina has expressed any interest in entering into such contractual relationships outside the proposed transaction. Moreover, any such arrangements would be challenging to negotiate and would face barriers that would hinder the information sharing required for a successful market access strategy. *See* PX7130 (Deverka (Expert) Dep. at 182:1-184:1) (identifying "real constraints about sharing of data across companies").

[244] PX6066 (Email from Molly Jamison to Nicholas Widnell and Sam Fullitonre: In the Matter of Illumina, Inc. and Grail, Inc. (Docket No. 9401) w/ Attach: Aravanis Notes_CONFIDENTIAL.pdf).

[245] *Id.*

[246] RX3282, GRAIL Corporate Fact Sheet.

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.[247]

(4) The Combined benefits of acceleration are enormous.

Respondents will show that the combination of these efficiencies and the acceleration expected as a result, will save thousands of lives. Accelerating access to Galleri will result in millions more patients being tested with Galleri sooner, allowing more cancers to be caught potentially in earlier stages when they may be cured. Respondents have in fact estimated that with a one year acceleration, an additional 10 million tests would be performed in the U.S. over a nine-year period (2022-2030)—a 34% increase in the number of test that would be expected to occurred absent the transaction.[248] This in turn translates to a reduction of between 7,429 and 10,441 deaths in the United States alone.[249]

As the parties have repeatedly affirmed, this transaction will save lives. While the value of a human life is in many ways immeasurable, economists and policymakers routinely use a dollar value of remaining life to estimate the "value of a statistical life".[250] Applying this metric, the acceleration benefits of this proposed transaction using a conservative estimate results in benefits of $37.1 billion.[251] No costs associated with achieving these benefits could outweigh

[247] RX3867 (Deverka Report) ¶ 120.

[248] RX3864 (Carlton Report) ¶ 119.

[249] RX3864 (Carlton Report) ¶ 119 (see Table 3); see also n. 291 (acknowledging that these calculations only include U.S. lives. Dr. Carlton acknowledges that acceleration will also save lives in other countries resulting in benefits that "would be more than double what [Carlton] calculated").

[250] RX3864 (Carlton Report) ¶ 120 (citing W. Kip Viscusi (2018), "Best Estimate Selection Bias in the Value of a Statistical Life," Journal of Cost-Benefit Analysis, 9: 205-46.).

[251] RX3864 (Carlton Report) ¶ 120.

the value of lives saved.[252] Because acceleration is focused on ensuring that Galleri is reimbursed and covered through public and private payors sooner, the proposed transaction is sure also to lead to increased access of a potentially life-saving test to underserved communities that often have worse cancer outcomes under the current standard of care.[253] Saving lives and potentially reducing health disparities are enormous benefits.

These acceleration benefits will not only accrue to GRAIL, but also to other test developers. Future test developers will benefit from Illumina accelerating a pathway to broad adoption of an MCED test. Galleri is an innovative test that has no precedent. This fact will make receiving regulatory approvals and payor coverage more challenging for GRAIL because there is no charted pathway for GRAIL to follow or precedent for the FDA to use to evaluate Galleri. However, once Galleri is approved it will pave the way for future test developers to approach the FDA. The evidence will show that similar medical devices that follow an innovative first-of-its-kind device often receive approval faster than the initial device.[254] The same is likely to be true of payor approval. Once Galleri has generated clinical utility data that can demonstrate the benefits of a multi-cancer screening test, future test developers will be able to more readily follow Galleri's approval.[255]

iii. The Transaction Will Create R&D Efficiencies

Respondents will show that significant R&D efficiencies will be generated by combining GRAIL's expertise in methylation, data science and software development with

[252] Complaint Counsel argues that the "opportunity costs to reallocate Illumina's resources would be high" (CC Br. 108), but the cost of shifting employees and resources would not reach anywhere close to $37 billion.

[253] RX3867 (Deverka Report) ¶ 104 (identifying known cancer health disparities in racial/ethnic minorities in the United Sates).

[254] RX3858 (Serafin Decl.) ¶¶ 57-59.)

[255] RX3858 (Serafin Decl. ¶¶ 53–55.)

Illumina's complementary expertise in sequencing and bioinformatics. [redacted].[256] [redacted].[257]

While these efficiencies are hard to quantify numerically, they are undoubtedly real and create the possibility for benefitting patients and consumers immensely. Illumina's past acquisition of Verinata provides an example of the benefits that can result from such synergies. When Illumina acquired Verinata, over 100,000 women had taken Verinata's Verifi NIPT test. In a handful of cases, a signal was detected in the mother's blood that was initially believed to be a false signal indicating a genetic abnormality in the fetus. Researchers at Illumina analyzed that data and discovered that the NIPT test had detected circulating tumor DNA (ctDNA) fragments present in the mother's bloodstream. Verinata's NIPT test had, incidentally, detected cancer in the blood, albeit at a late stage. From there, Illumina set out to achieve one of the most critical goals of cancer care—detecting cancer in the blood at its earliest stages. A few years later, it

[256] RX1994 at 57 (Email from S. Muppaneni to P. Febbo enclosing Slide Deck re Illumina Strategic Plan 2021-2025, Board Discussion Document).

[257] RX1994 at 45 (Email from S. Muppaneni to P. Febbo enclosing Slide Deck re Illumina Strategic Plan 2021-2025, Board Discussion Document).

formed GRAIL to pursue that moonshot objective.[258] And today, GRAIL is offering its cancer screening test, Galleri, to patients.

Complaint Counsel provides two principal arguments against the potential for R&D efficiencies. *First*, they argue that there is insufficient verification of the potential R&D efficiencies. (CC Br. at 108-109.) But the fact that significant R&D efficiencies arose from the acquisition of Verinata provides a strong showing that similar efficiencies are likely to occur here. The Horizontal Merger Guidelines, which Complaint Counsel rely on, and case law state that "efficiency claims substantiated by analogous past experience are those most likely to be credited." Merger Guidelines § 10; *see also Deutsche Telekom AG*, 439 F. Supp. 3d at 212. *Second*, Complaint Counsel argues that the efficiency is not merger specific. (CC Brief at 109.) But the discovery of the potential of blood-based cancer screening using NGS through the Illumina's acquisition of Verinata is strong evidence that vertical mergers can – and this one will – create real R&D efficiencies.

iv. The Transaction Will Result in Cost Savings and Lower Prices to Consumers

(1) Elimination of Double Marginalization

Elimination of Double Marginalization or EDM is a well-documented efficiency from vertical transactions that occurs when an upstream firm acquires a downstream firm to which it supplies inputs. As explained by Respondents' expert, Dr. Carlton:

> EDM benefits arise when an upstream firm with market power acquires a downstream firm with market power to which it supplies inputs. When the upstream and downstream firms operate in markets that are not perfectly competitive, each firm sets its optimal price at a markup over marginal cost. When the upstream and downstream firms merge, there is a single firm with the

[258] RX3343 at -24–25 (Illumina submission to FTC dated December 31, 2021, "Non-Invasive Prenatal Testing ("NIPT")).

> marginal costs of what was formerly the upstream firm and which faces the same demand curve as the former downstream firm. Thus, the margin of the upstream firm is internalized and there is an effective reduction in the marginal cost of producing the downstream product; put differently, the merger leads a profit maximizing firm to eliminate the upstream margin from its downstream pricing decision and to reduce the price of the downstream good.

Carlton Report at 67-68. This principle is not controversial. As the FTC's Vertical Merger Guidelines Explain, "[d]ue to the elimination of double marginalization, mergers of vertically related firms will often result in the merged firm's incurring lower costs for the upstream input than the downstream firm would have paid absent the merger. This is because the merged firm will have access to the upstream input at cost, whereas often the downstream firm would have paid a price that included a markup." Vertical Merger Guidelines at 11. It is widely acknowledged that a vertical merger cannot be shown to be anticompetitive without balancing any alleged anticompetitive effects against likely EDM efficiencies. *See* Christine Wilson, Reflections on the 2020 Draft Vertical Merger Guidelines and Comments from Stakeholders, *Remarks at the DOJ Workshop on Draft Vertical Mergers* (March 11, 2020) at 6 ("Consequently, my view is that any RRC analysis must simultaneously – and symmetrically – address EDM. Evidence, whether qualitative or quantitative, that a merger is likely to generate large RRC effects is unavailing without a concurrent EDM analysis.").

Respondents will show, through their experts at trial, that the consumer surplus likely to result from the transaction for the period from 2020 to 2030 is $627.9 million.[259]

[259] RX3864 (Carlton Report) ¶ 104 (Table 1).

Complaint Counsel raises three arguments against EDM – all without merit.

First, Complaint Counsel argues that Respondents have failed to quantify EDM. (CC Br. 110–111.) This argument assumes that it is Respondents and not Complaint Counsel's burden to quantify and balance EDM. But even if it were Respondents' burden, Respondents' experts have quantified EDM with greater particularity than Complaint Counsel has quantified any alleged harm. *Second*, Complaint Counsel's expert argues that EDM is not merger specific because Respondents could achieve these procompetitive benefits today, given the complex contracts that already exist between the parties. (CC Br. 111–112.) This assertion, however, follows from the Dr. Scott Morton's unsupported assumption that EDM can easily be eliminated by contract. And that reasoning would eliminate the rationale for every vertical merger, as all EDM benefits could be achieved by contract under Dr. Scott Morton's theory, and thus flies in the face of longstanding economic literature, case law on vertical mergers and the Vertical Merger

Guidelines. *See e.g.*, *AT & T Inc.*, 310 F. Supp. 3d at 193 ("EDM effect is 'generally accepted as a potential procompetitive benefit resulting from vertical mergers'") (quoting the DOJ's proposed findings of fact). *Finally*, Complaint Counsel asserts that its economic expert has "accounted for the possibility of EDM" and concluded that it is "easily outweigh[ed]" by the potential harm. (CC Br. at 112.) Such ipse dixit is plainly insufficient to carry Complaint Counsel's burden of proof to show that the transaction will substantially lessen competition.

(2) Elimination of Royalties

The proposed transaction will also lead to significant efficiencies in the form of reduced royalties that GRAIL is currently required to pay to Illumina. When it spun off GRAIL in 2017, Illumina retained partial ownership of the company and signed a supply agreement that obligated GRAIL to pay Illumina a royalty calculated as a percentage of GRAIL's revenues. Under that agreement, GRAIL is committed to pay a royalty of [redacted] of all oncology revenues to Illumina until it has paid cumulative royalties of [redacted] at which point the royalty rate will decline to [redacted].[260]

The proposed transaction will eliminate a portion of these royalties. GRAIL's royalty payments to Illumina will cease, and Illumina will issue contingent value rights (CVRs) to certain former GRAIL shareholders and equity award holders. Any GRAIL shareholder or equity award holder can choose to receive merger consideration in the form of a mix of cash and stock or a mix of cash and stock and one or more CVRs (the "CVR Consideration"). Holders of a CVR are entitled to a percentage of GRAIL's revenue streams from specified commercial activities. [redacted]

[260] RX1371 at -10–12 (Amended and Restated Supply and Commercialization Agreement between Illumina, Inc. and GRAIL, Inc.).

[redacted].[261] [redacted] Respondents will show, through their experts at trial, that U.S. consumer surplus from the elimination of these royalties during the years 2022-2030 is $136.9 million.[262]

[redacted]

As with EDM, Complaint Counsel does not take issue with the above math or the reduction in royalties. Instead, Complaint Counsel's economic expert argues that this efficiency could be achieved now by negotiation between the parties. (CC Br. at 111–112.) [redacted]

[261] RX0699 at 164–165 (Agreement and Plan of Merger among Illumina, Inc., SGQ OPS, Inc., SGQ OPS, LLC., and Grail, Inc.(executed) (GRAIL-DOC-00993973)).

[262] RX3864 (Carlton Report) ¶¶ 110–111 (Table 2).

[redacted]

(3) Supply Chain Efficiencies

The merger will also allow Illumina and GRAIL to achieve significant supply chain efficiencies through a shared supply agreement, shared supplier relationships and a shared IT system. Illumina will be able to leverage its already strong supplier relationships and IT infrastructure to lead to 3-5% annual cost savings in external spend, improved time to market, supply chain optimization, IT system cost avoidance and improved product quality. Respondents will show, through their experts and other evidence at trial, that these cost savings are approximately $80-150M over a 10-year period.[263]

(4) Laboratory Operations Efficiencies

Significant efficiencies will also arise through GRAIL's access to Illumina's lab operations. Illumina is an experienced operator of CLIA-certified laboratories at scale. Through its Illumina Lab Services division, Illumina offers clinical sequencing services at its CLIA-certified laboratories in San Diego and Foster City, California, including NIPT testing and direct-to-consumer ("DTC") genomic testing, as well as more recently COVID testing. The capacity and experienced personnel at these laboratories can be used for Galleri in the event there are delays in constructing and obtaining the required registrations and certifications for GRAIL's planned North Carolina laboratory, or unforeseen issues affecting laboratory

[263] PX2613-002 (Appendix A: Illumina/GRAIL Efficiency Analysis (FTC_ILMN_00049198).

operations in the future. Likewise, Illumina's laboratories could be used if demand for Galleri exceeds expectations and additional capacity is needed.

Illumina is well-equipped to help GRAIL navigate unforeseen issues that may come up with its laboratory development or operations, and ensure that they do not impact GRAIL's ability to provide Galleri and other tests to each patient who needs one. Illumina's laboratory team has experience rapidly scaling testing, which it had to do when its DTC business expanded from processing roughly 200,000 samples annually to over 4 million samples annually over the course of just a few years.[264] Illumina also has experience moving tests from one laboratory to another with minimal down time, as it did when it moved its NIPT business from its Redwood City laboratory to its Foster City laboratory. It has ample experience efficiently procuring laboratory equipment and handling inventory, and dealing with issues that inevitably come up in a clinical laboratory. Thus, if GRAIL needs to move some of its testing between labs, or needs to scale more rapidly than anticipated, it will benefit greatly not just from the capacity available at Illumina's labs, but from collaborating and problem-solving with Illumina's experienced laboratory staff and leadership who have dealt with such issues already.

In addition, Illumina has experience operating at scale within established quality and regulatory compliance frameworks, such as International Organization for Standardization ("ISO") certifications and standards, and current good manufacturing practices ("cGMPs"), with which GRAIL will need to comply under FDA requirements. GRAIL will benefit from Illumina's extensive experience in this area, which will reduce timing risks as GRAIL scales its operations under these complex frameworks.

[264] RX1599-11 (Clinical Genomics Laboratory Services (CGLS) 101 (ILMN-FTCVOL_00537333)).

The use of Illumina's lab operations will also result in specific cognizable cost savings. Illumina's high throughput, high complexity laboratory services operations will enable GRAIL to benefit from Illumina's laboratory automation, highly skilled laboratory staff, efficient capacity utilization, error and sample minimization and workflow optimization. Respondents will show, through their experts and other evidence at trial, that these cost savings are approximately $58.5M over a 10-year period.[265]

v. Complaint Counsel Cannot Show the Alleged Anticompetitive Effects Outweigh the Procompetitive Effects of the Transaction.

As explained above, Complaint Counsel bears the burden to show that the proposed transaction is anticompetitive. Because this is a vertical transaction, Complaint Counsel must show that the alleged anticompetitive effects outweigh the procompetitive effects of this transaction. *U.S. v. AT&T Inc.*, 310 F. Supp. 3d at 195. Respondents will show, at trial, that the procompetitive efficiencies associated with this transaction are conservatively valued in the billions of dollars. Complaint Counsel has done nothing to quantify the cost to consumers associated with the alleged anticompetitive effects or done anything to balance those effects against the procompetitive benefits. Accordingly, they have not met their burden to show the transaction is likely to lessen competition.

CONCLUSION

For the foregoing reasons, the evidence presented at trial and admitted to the record will establish that Complaint Counsel has failed to meet their burden to show that the Proposed Acquisition violates Section 7 of the Clayton Act and Section 5 of the FTC Act.

[265] PX2613-004 (Presentation: Appendix A: Illumina/GRAIL Efficiency Analysis (FTC_ILMN_00049198).

Dated: August 18, 2021

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CERTIFICATE OF SERVICE

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I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 18, 2021

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EXHIBITS CITED TO IN RESPONDENTS' PRE-TRIAL BRIEF

(All Exhibits Served via FTP Transfer – Aggregate File Size Over the Limit to E-File)

RX0003	RX3117	RX3836
RX0007	RX3185	RX3837
RX0008	RX3196	RX3843
RX0009	RX3244	RX3844
RX0193	RX3258	RX3845
RX0381	RX3262	RX3847
RX0383	RX3270	RX3848
RX0415	RX3282	RX3849
RX0481	RX3340	RX3850
RX0485	RX3343	RX3852
RX0487	RX3356	RX3858
RX0518	RX3361	RX3861
RX0519	RX3365	RX3864
RX0520	RX3422	RX3866
RX0582	RX3441	RX3867
RX0699	RX3473	RX3868
RX0744	RX3498	RX3869
RX0847	RX3515	RX3871
RX1096	RX3532	RX3899
RX1100	RX3544	PX2613
RX1371	RX3549	PX4381
RX1540	RX3551	PX5027
RX1599	RX3589	PX5030
RX1699	RX3612	PX6066
RX1914	RX3613	PX6090
RX1994	RX3619	PX6091
RX2305	RX3621	PX6092
RX2330	RX3637	PX6093
RX2416	RX3638	PX7084
RX2437	RX3663	PX7092
RX2557	RX3694	PX7099
RX2584	RX3701	PX7130
RX2680	RX3800	
RX2697	RX3811	
RX2698	RX3815	
RX2703	RX3817	
RX2713	RX3818	
RX2731	RX3820	
RX2732	RX3822	
RX2761	RX3823	
RX2762	RX3824	

RX2764	RX3826	
RX2765	RX3827	
RX2766	RX3828	
RX3042	RX3831	
RX3060	RX3833	
RX3062	RX3835	