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' POST-TRIAL BRIEF

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Respondents Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") respectfully submit this post-trial memorandum in opposition to Complaint Counsel's complaint, claims and allegations concerning Illumina's acquisition of GRAIL, which was entered into on September 20, 2020, and closed on August 18, 2021 (the "Transaction").

PRELIMINARY STATEMENT

This is a case about a vertical merger that reunited a next generation sequencing ("NGS") company, Illumina, with the company it founded, GRAIL, in an effort to revolutionize cancer care. It is widely recognized that vertical mergers rarely harm competition and are typically procompetitive. The overwhelming evidence showed that the Transaction is a procompetitive vertical merger that will generate extraordinary benefits, particularly by accelerating the adoption of GRAIL's multi-cancer screening test, Galleri, and thus saving lives. Yet, Complaint Counsel seeks to unwind the Transaction on the misguided theory that it could harm competition for screening tests that do not yet exist and may never come to market. Complaint Counsel came nowhere close to carrying its burden of proof at trial: it failed altogether to prove that the Transaction will substantially lessen competition in any cognizable antitrust market. In fact, the Transaction will do just the opposite. Thus, Complaint Counsel's claims should be rejected as contrary to fact, law and common sense.

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 six years ago with the goal of developing an early screening test for multiple cancers. In 2017, Illumina reduced its investment in GRAIL so that it was no longer controlled by a public company and could operate as a biotech startup with the "freedom to fail" as it embarked on a moon-shot mission to develop a multi-cancer early screening test. Since that time, GRAIL has combined an "atlas" of cancer signals in the blood with a machine learning

platform to develop a one-of-a-kind test, Galleri, that has demonstrated it can simultaneously screen for more than 50 types of cancer in asymptomatic patients and accurately localize the cancer in positive cases *(i.e.*, detect cancer signal of origin). GRAIL launched Galleri as a laboratory developed test ("LDT") in the United States in June 2021, but faces significant hurdles to wide-scale commercialization, including obtaining regulatory approvals, payor reimbursement, and production and distribution of its test at scale. Illumina is uniquely situated to help Galleri clear those hurdles. The combined company will usher in a new era of cancer screening, accelerating the adoption of Galleri at scale, reducing the cancer burden in the U.S. and worldwide, and saving thousands of lives and many billions of dollars by reducing that burden sooner and at lower costs.

In seeking to unwind the Transaction, Complaint Counsel not only turns a blind eye to its benefits, but also it asks this Court to do what no court ever has. Complaint Counsel asks the Court to undo a vertical merger that will save countless lives and billions of dollars, where (1) the acquiring company founded the target only a few years before and has always owned a sizeable stake in it; (2) the target has the only product in a new market, and no one knows whether and when (if ever) any reasonably close alternative will be available; (3) Complaint Counsel did not do the work necessary to prove either a cognizable antitrust market or a likely risk of foreclosure; (4) Illumina made a binding offer that precludes any realistic prospect of anticompetitive effect and consents to the entry of an order prohibiting any anticompetitive conduct; and (5) the overwhelming evidence, including testimony from three former chief economists of the United States Department of Justice ("DOJ") demonstrates that the FTC's case puts a new and speculative approach to antitrust before near-certain, life-saving benefits. Further, as a purely vertical merger, the Transaction does not eliminate any competitor

from any relevant market—it is undisputed that there are no fewer competitors in any upstream market, nor any fewer competitors in any downstream market, as a result of the Transaction. No wonder Complaint Counsel dropped the complaint it filed in federal court in favor of an administrative proceeding during which the Commission sought to change the rules midstream (by withdrawing its vertical merger guidelines) and in which the Commission will be the ultimate administrative arbiter of its own allegations.

But even on its own turf, Complaint Counsel faces a heavy burden in opposing the Transaction. Because the Transaction is a purely vertical merger and does not eliminate any competitor in any upstream or downstream market, Complaint Counsel cannot rely on any shortcuts or presumptions of anticompetitive effects that may be available in a horizontal case. Rather, Complaint Counsel must prove that, "at this time", and in the context of the current state of this "remarkably dynamic industry", the Transaction *itself* is likely to "*substantially* lessen competition" in a manner greater than the benefit conferred by the Transaction's procompetitive effects. *United States. v. AT&T Inc.* (*AT&T I*), 310 F. Supp. 3d 161, 194 (D.D.C. 2018), *aff'd sub nom. United States v. AT&T, Inc.* (*AT&T II*), 916 F.3d 1029 (D.C. Cir. 2019) (emphasis added). To meet this burden, Complaint Counsel must show that the considerable benefits of the transaction, including countless lives saved, would be substantially outweighed by non-speculative, real-world anticompetitive effects. *Id.* at 194–95; *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004). That it cannot do.

As is further discussed below, Complaint Counsel's challenge to the Transaction should be rejected for six primary reasons: (1) Complaint Counsel failed to prove the requisite antitrust markets; (2) Complaint Counsel failed to prove the Transaction is likely to substantially lessen competition; (3) Illumina's Open Offer precludes any potential anticompetitive effects; (4)

the Transaction will generate merger-specific efficiencies that more than offset the alleged harm; (5) the FTC's challenge violates the U.S. Constitution in multiple respects; and (6) the overwhelming weight of the evidence demonstrates the Transaction is good for competition, good for the market, and good for patients, and undermines Complaint Counsel's case, which is based on "evidence" that is inadmissible and/or deserving of no weight.

Failure to Prove Relevant/Related Markets. Complaint Counsel alleges a relevant product market consisting of all "MCED tests". According to Complaint Counsel, this market consists of (i) a commercialized MCED test (Galleri) that can screen for more than 50 types of cancer and identify cancer signal of origin in positive cases—a feature the FDA believes is essential for an MCED test—and (ii) other putative tests in development that will supposedly screen for more than one cancer at some point in the future if and when they are launched. However, Complaint Counsel failed to *prove* any such market. While Galleri is available for sale in the United States, there is no other test like it commercially available or even in development. Complaint Counsel thus failed to show that Galleri belongs to the same antitrust market as any other test, including those it identifies that are in development, whose predicted features and functions are nothing like Galleri, and whose launch timelines are unknown. Complaint Counsel's proposed market (1) is impermissibly speculative and both over and under-inclusive; (2) disregards "interchangeability and cross-elasticity of demand"; (3) runs counter to the Supreme Court's *Brown Shoe* factors; (4) cannot be shown to satisfy the hypothetical monopolist test; and (5) depends on the FTC's subjective and changing policy assessments, rather than established law and objective evidence. (*See* Section I.A below).

Complaint Counsel also failed to prove a "related product market". Complaint Counsel contends it is not required to prove a related product market, suggesting that it is

sufficient for Complaint Counsel simply to declare one. That is wrong. While Complaint Counsel describes the related product market as consisting of NGS products and services (apparently because that is the only segment in which Complaint Counsel believes Illumina has substantial market power), it makes no effort to define or prove the contours of any such alleged market. In any case, even if "NGS products and services" were a proper related product market, there are currently non-Illumina NGS platforms available for cancer screening, and there are non-Illumina NGS platforms in development, whose features, functions and launch timelines are more certain than the speculative screening tests Complaint Counsel declares to be in the downstream market. Customers can port tests developed on Illumina's platform to other platforms, which undercuts Complaint Counsel's theory that Illumina has the ability to foreclose such customers. Complaint Counsel's failure to prove either a relevant product market or a related product market dooms its case from the outset. (*See* Section I.B below).

No Substantial Lessening of Competition. Even if Complaint Counsel had carried its burden to prove both a relevant product market and a related product market, it failed to prove the Transaction will substantially lessen competition, the touchstone of any claim under Section 7 of the Clayton Act. Complaint Counsel alleges that the Transaction will harm competition because it purportedly gives Illumina the ability and incentive to foreclose GRAIL's putative rivals (*i.e.*, other purported MCED test developers). In so doing, however, Complaint Counsel applies the wrong standard. Longstanding case law and economic theory acknowledge that, unlike horizontal transactions, vertical transactions do not eliminate a competitor from any market, are rarely anticompetitive, and generate efficiencies that benefit consumers and must be balanced against any potential harm. Yet, Complaint Counsel takes no account of the

procompetitive benefits of the Transaction and thus fails to balance the alleged harm against the undisputed efficiencies.

Moreover, by any standard, Complaint Counsel's foreclosure theory falls short, because it: (1) fails to account for the fact that Illumina attempting to foreclose GRAIL's putative rivals would hurt Illumina's NGS sales and reputation; (2) disregards the fact that NGS costs are today a small part, and within the next few years will be a very small part of MCED test revenues and margins going forward; (3) offers no basis to predict any material diversion to Galleri from the alleged foreclosure strategy; (4) overlooks viable alternatives to Illumina's NGS products for MCED development; and (5) misunderstands—and in some cases completely ignores—Illumina's prior successful vertical integrations. Complaint Counsel simply did not do the work necessary to justify killing a life-saving transaction. (*See* Section II below.)

Disregard of the Open Offer. Because Illumina has no intention of foreclosing GRAIL's putative rivals (and no incentive to do so), it made a binding Open Offer to all of its oncology customers that removes any realistic prospect that the Transaction could have an adverse impact on competition. Under the Open Offer, Illumina is contractually forbidden from anticompetitively disadvantaging GRAIL's putative rivals vis-à-vis GRAIL. Among other things, the Open Offer:

- Requires Illumina to provide customers with an uninterrupted supply of the sequencing instruments and consumables;
- Prohibits Illumina from increasing the price of any of the supplied sequencing instruments or consumables;
- Compels Illumina to decrease the cost of sequencing on Illumina's highest throughput sequencing instrument, using the highest throughput consumable, by at least 43% for all customers, by 2025;
- Forbids Illumina from sharing any confidential information received from another customer with GRAIL;

- Commits Illumina to a bi-annual audit conducted by an independent third-party auditor to confirm compliance with the terms of the Open Offer; and
- Mandates baseball-style arbitration as a means of dispute resolution, where the arbitrator is expressly authorized to order *any* relief necessary to restore the status quo prior to Illumina's alleged breach, including monetary and/or injunctive relief, and the arbitrator is expressly directed to take into account, and reflect in any decision, that the purpose of the Open Offer is to allay any concerns relating to the Transaction.

Further underscoring its commitment to this binding offer, Illumina consents to the inclusion of these privately enforceable obligations in an enforceable consent order. Many of Illumina's customers—including certain purported MCED test developers that testified on behalf of Complaint Counsel—have already accepted the Open Offer or incorporated its terms into supply agreements. Complaint Counsel mischaracterizes the Open Offer, understates the protections it offers, and speculates that Illumina will find some way to circumvent its legal obligations, as if Illumina could willfully breach its contracts with impunity, and as if the threat of an arbitration award that could include both injunctive relief and monetary damages has no impact on Illumina's incentives.

Complaint Counsel's challenge to the Transaction misses the mark because (1) it ignores the present and future impact of the Open Offer on Illumina's incentive and ability to foreclose GRAIL's putative rivals; (2) its criticisms of the Open Offer ignore the record, underestimate contractual remedies and are otherwise misplaced; and (3) the Open Offer alone, and in combination with Illumina's proposed consent order, is more than sufficient to resolve any legitimate concern about future foreclosure of still non-existent products. (*See* Section III below).

Overwhelming Evidence of Efficiencies. Even if the Transaction could be said to give Illumina the ability and incentive to harm competition, and even if the Open Offer were unable to eliminate the likelihood of harm, any supposed harm arising from the deal is easily

outweighed by the efficiencies it will generate. The overwhelming and unrefuted evidence showed that the Transaction will result in numerous, merger-specific benefits, including in particular that it will save tens of thousands of lives (in the U.S. alone, and many more throughout the world). Specifically, the reunion of Illumina and GRAIL (1) will accelerate market access to a life-saving test; (2) will lead to new innovations from synergistic R&D; (3) eliminates a royalty that GRAIL was otherwise contractually required to pay to Illumina; (4) eliminates double marginalization; and (5) will lead to supply chain, operational and international efficiencies, resulting in lower prices and faster testing for patients. While it is difficult (if not impossible) to value human life in monetary terms, the benefits of the Transaction can be reasonably estimated to exceed $30 billion. Complaint Counsel has failed to show that any alleged harm outweighs these enormous benefits. Instead, Complaint Counsel's challenge to the Transaction elevates its new and untested views on antitrust enforcement policy above long-standing antitrust law and the interests of patients, consumers, and the healthcare system. (*See* Section IV below).

Unconstitutionality of the Challenge. In addition to its disregard of long-standing antitrust precedent, Complaint Counsel's challenge to the Transaction violates Illumina's and GRAIL's rights under Article II and the Due Process and the Equal Clauses of the U.S. Constitution. The FTC Act vests the FTC with law enforcement authority but renders its Commissioners and ALJs unaccountable to the President by prohibiting him/her from removing them at will, creating an unconstitutional dual layer of protection, in violation of Article II. The FTC Act violates the Due Process Clause by authorizing an administrative hearing process in which the FTC simultaneously acts as prosecutor, judge and jury. And the FTC Act violates the Equal Protection Clause by irrationally depriving a merging party subject to FTC proceedings of

the structural and procedural protections it would possess in a challenge brought by the DOJ. (*See* Section V below).

Overwhelming Weight of the Evidence. Finally, Complaint Counsel's case flies in the face of the overwhelming proof and rests on "evidence" that is inadmissible and deserving of no weight. Complaint Counsel's case disregards the unrebutted testimony of witnesses from both Illumina and GRAIL and from disinterested third parties. It also ignores the largely unchallenged testimony of eight experts, called by Respondents, including three former chief economists of the DOJ and the only two practicing physicians to be called as witnesses. Instead, Complaint Counsel rests on (1) the opinions of three economists who are either unqualified to offer the opinions they provide or failed to support their opinions with reliable evidence; (2) selective citations from third party test developers who have an interest in derailing the Transaction for their own gain; and (3) Investigational Hearing ("IH") transcripts and other documents that are unreliable and/or inadmissible. (*See* Section VI below.)

In sum, Complaint Counsel's challenge to the Transaction disregards established law, ignores the factual record, and defies common sense. It ignores the law by substituting speculation for evidence, seeking to shift the burden of proof to Respondents, and analyzing a vertical merger with the methodology reserved for horizontal mergers. It ignores the factual record by dismissing substantial efficiencies supported by the unrefuted trial testimony of every Illumina and GRAIL witness who addressed the subject; and discarding undisputed evidence undermining Complaint Counsel's foreclosure theory. And it defies common sense by seeking to kill a transaction that will unquestionably generate enormous benefits, based on a speculative concern that Illumina might disadvantage the yet-to-be developed test of a purported GRAIL rival in the future, despite overwhelming evidence that Illumina has no ability and incentive to

do so, and the Open Offer prevents it from doing so. Tellingly, Complaint Counsel was unable to present a single expert witness with any expertise whatsoever in the NGS or MCED fields—because an expert in either of those fields would never support Complaint Counsel's theory of the case.

For these reasons, and as is further discussed below and in Respondents' Proposed Findings of Fact and Conclusions of Law (submitted herewith), Complaint Counsel's challenge to the reunion of Illumina and GRAIL should be rejected, and judgment should be entered in favor of Respondents.

STATEMENT OF FACTS

The Court held trial in this matter over 18 days (excluding the final pretrial conference and eight trial depositions) from August 24, 202,1 to September 24, 2021. Collectively, the parties called 30 fact witnesses and 10 expert witnesses. All of the witnesses testified live via Zoom, except, at the Court's urging, a number of expert witnesses testified by trial deposition and their testimony has been presented to the Court by video and transcript.

The overwhelming testimonial, documentary, and expert evidence demonstrated that the reunion of Illumina and GRAIL will generate efficiencies of great significance—it will, for example, save thousands of lives and generate tens of billions of dollars of value for consumers—and that Complaint Counsel's theory of harm is misguided. Complaint Counsel asks the Court to undo the Transaction and forego all of its benefits based on its stated concern that the Transaction may enable and incentivize Illumina to disadvantage GRAIL's putative rivals if and when they launch an MCED test that competes with GRAIL's Galleri test. Not only is that concern misplaced, but also it is contrary to the unrefuted evidence of record and legally flawed for multiple, independent reasons, which we describe below.

The facts most pertinent to this case are set out in detail in Respondents' Proposed Findings of Fact and Conclusions of Law, submitted herewith. We respectfully submit that those facts, combined with applicable law, compel a decision in favor of Respondents.

As shown in Respondents' Proposed Findings, the testimony of Illumina and GRAIL witnesses debunks Complaint Counsel's case. These witnesses, including Francis deSouza, Illumina's CEO; Alex Aravanis, Illumina's CTO and founder and former head of R&D at GRAIL; Jay Flatley, Illumina's former Chairman and CEO; Phil Febbo, Illumina's Chief Medical Officer; Joydeep Goswami, Illumina's Chief Strategy and Corporate Development Officer; Ammar Qadan, Illumina's Vice President and Global Head of Market Access; Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Region; John Leite, Illumina's former Vice President of Clinical Business Development; Hans Bishop, GRAIL's then-CEO; Josh Ofman, GRAIL's President and Chief Medical Officer and then-Head of External Affairs; Aaron Freidin, GRAIL's then-Senior Vice President of Finance and current Chief Financial Officer; Arash Jamshidi, GRAIL's former Senior Vice President of Data Sciences; and Chris Della Porta, GRAIL's Head of New Business Partnerships & New Product Strategy, offered reliable testimony that the Transaction will generate huge efficiencies including saving lives; that it will not give Illumina any incentive to foreclose GRAIL's rivals; and that the Open Offer fully addresses Complaint Counsel's concerns. (*See* PFF ¶¶ 1216–1688.)

The testimony of disinterested third parties is similarly destructive to Complaint Counsel's case. Dr. William Cance, the Chief Medical and Scientific Officer of the American Cancer Society (ACS) (whom Complaint Counsel called in its case), testified that the ACS has done no analysis that shows the acquisition would result in any loss of innovation in MCED tests or that it would raise the costs of developing MCED tests. (PFF ¶ 1920.) Matthew Strom,

Managing Director with Morgan Stanley's healthcare investment banking group, debunked Complaint Counsel's contention that GRAIL could have realized the benefits of the Transaction through an IPO. (PFF ¶¶ 1855–1856.) Jorge Velarde, Senior Vice President of Corporate Development and Strategy at Singular Genomics ("Singular"), testified that Singular (which one of GRAIL's purported rivals, Exact Sciences, has invested in) intends to launch an NGS platform (the G4 sequencer) by the end of 2021 (which it has since launched), refuting Complaint Counsel's claim that there are no near term alternatives to Illumina. (PFF ¶ 1903.)

Although the burden of proof rests with Complaint Counsel, Respondents offered the testimony of eight experts, including:

- Dr. Dennis Carlton, Professor of Economics at the University of Chicago Booth School of Business and a former Deputy Assistant Attorney General for Economic Analysis at the Antitrust Division of the DOJ, who testified that the Transaction is unlikely to lessen competition, since Illumina will not have an incentive and ability to foreclose GRAIL's potential rivals; and that the Transaction will generate significant efficiencies and save lives. (PFF ¶¶ 1934, 1938.)

- Dr. Robert Willig, Professor Emeritus of Economics and Public Affairs at the Woodrow Wilson School at Princeton University, and former Deputy Assistant Attorney General for Economics in the Antitrust Division of the DOJ, who concluded

that Complaint Counsel has not reliably defined a relevant market (PFF ¶¶ 2009–13), that Complaint Counsel's theories of anticompetitive effects are belied by the actions of firms in the marketplace (PFF ¶¶ 2017–18), and that Complaint Counsel's bargaining example is untethered to the facts of the marketplace and is not robust (PFF ¶¶ 2019–2021). Dr. Willig was unable to testify at the live hearing, but his written report and deposition are in evidence.

- Dr. Michael Katz, Professor Emeritus at the Haas School of Business & Department of Economics at University of California and a former Deputy Assistant Attorney General for Economic Analysis at the Antitrust Division of the DOJ, who testified at the live hearing that Complaint Counsel has not reliably defined relevant upstream or downstream markets (PFF ¶¶ 2044–48), that Complaint Counsel's theories of anticompetitive effects are belied by the actions of firms in the marketplace (PFF ¶¶ 2049–2053), and that Complaint Counsel's bargaining example is untethered to the facts of the marketplace and is not robust (PFF ¶¶ 2054–56).

- Dr. Richard Cote, Professor of Pathology and Immunology and Chair of the Department of Pathology and Immunology at the Washington University School of Medicine, who testified that the evidence to date shows that other cancer screening test developers are currently developing tests that, if ever launched, will be complements to Galleri, rather than substitutes (PFF ¶ 1962), and that there are alternative NGS platforms today that support multi-cancer screening tests and there are likely to be many more in the near future. (PFF ¶ 1964.)

- Dr. Richard Abrams, a primary care physician and founder of Colorado Preventative Medicine, who testified that the most important attributes of an MCED test for primary care physicians will be a test's ability to detect the presence of a cancer and its signal of origin, the number of cancers detected and the opportunity to treat early cancer (PFF ¶ 2034); that Galleri would be used among asymptomatic patients looking to test for a broad array of cancers (PFF ¶ 2038); and that it is unlikely that a primary care physician would treat a test that does not detect cancer signal of origin as a substitute for Galleri (PFF ¶ 2038).

- Dr. Patricia Deverka, Deputy Director of the Center for Translational and Policy Research on Personalized Medicine at the University of California at San Francisco, who testified that Illumina will be able to help GRAIL overcome the challenges to, and accelerate, GRAIL obtaining insurance reimbursement for Galleri, enabling it to achieve broad market coverage earlier than GRAIL would be able to on its own. (PFF ¶ 1988.)

- Ms. Margaret Guerin-Calvert, President and Senior Managing Director of FTI Consulting's Center for Healthcare Economics and Policy, and a former Assistant Chief of the Economic Regulatory Section of the Antitrust Division of the DOJ, who has substantial experience with behavioral remedies in merger cases, and testified that the Open Offer covers the economically necessary set of terms to prevent the alleged competitive harm arising from the Transaction in both the short and long term; and

that the Open Offer has key attributes similar to, and has even more protections than. (PFF ¶¶ 1993–2001.)

- Mr. Robert Rock, Managing Director at AlixPartners, LLP, an expert on auditing, who testified that the auditing provision of the Open Offer is an effective monitoring mechanism that addresses the concerns raised by Complaint Counsel and third parties regarding the ability to monitor Illumina's compliance with the Open Offer terms. (PFF ¶ 2027.)

Complaint Counsel had no answer for the opinions of these experts. It offered instead the opinions of Dr. Fiona Scott Morton, Dr. Dov Rothman, and Dr. Amol Navathe. But the testimony of these purported expert witnesses is inadmissible and/or unreliable:

- Dr. Scott Morton's opinions on MCED technology, the viability of alternative NGS platforms, regulatory approval, and reimbursement, which are fundamental to her conclusions, should be disregarded because she lacks the scientific, regulatory and reimbursement expertise to opine on these matters. (PFF ¶¶ 2058–63.) Her market definition opinion should be rejected because she has failed to conduct any quantitative analyses and relies on her own, flawed qualitative assessment of a cherry-picked record. (PFF ¶¶ 2067–81.) And her opinion as to the related product market is flawed for some of the same reasons that doom her market definition opinion. (PFF ¶¶ 2082–96.) Much of Dr. Scott Morton's opinion is based upon speculation, a selective reading of the record, and impermissible weighing of the evidence that usurps the domain of the fact finder. (*See infra* Section VI.1.)

- Dr. Rothman lacks the expertise to opine on efficiencies related to the acceleration of Galleri's FDA approval and payor reimbursement, and his opinions on these topics should be given no weight. (PFF ¶ 2187.) Dr. Rothman's interpretation of what agency guidelines require to substantiate merger efficiencies, which is the crux of his opinion, should be given no weight because it invades the Court's province and constitutes improper legal opinion. (PFF ¶ 2191.)

- Dr. Navathe's opinions should be given no weight because, by his own admission, he lacks the expertise and experience to opine on FDA approval and payor reimbursement. (PFF ¶¶ 2140–49.) Moreover, having merely reviewed selected documents provided to him by Complaint Counsel, Dr. Navathe cannot properly testify regarding acceleration. (PFF ¶¶ 2170–76.) And witnesses such as Dr. Febbo, who have far more expertise than Dr. Navathe on the FDA issues on which he opines, demonstrated that Dr. Navathe's conclusions turn on fundamental misunderstandings of basic facts. Finally, like Dr. Rothman, Dr. Navathe's critique usurps the role of the Court insofar as he purports to opine whether Respondents made a sufficient showing of an efficiency.

STANDARD OF DECISION

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." *AT&T I*, 310 F. Supp. 3d at 194. 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 making that technology available 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); *In re Altria Grp., Inc.*, FTC No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive

conditions of a market five years in the future cannot reliably be predicted."); *see also FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1051 (8th Cir. 1999) ("Section 7 deals in probabilities not ephemeral possibilities.").

In addition, because the Transaction is purely vertical (by all accounts), Complaint Counsel "cannot use a short cut to establish a presumption of anticompetitive effect"; rather, it must make a "fact-specific" showing that the Transaction is anticompetitive. *United States v. AT&T, Inc.* (*AT&T II*), 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."). As discussed below (*infra* Sections II, IV), Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the Transaction.

Furthermore, Complaint Counsel cannot sustain its burden merely by showing that the Transaction may disadvantage some GRAIL's putative rivals vis-à-vis GRAIL—for example, as a result of GRAIL becoming a more efficient competitor through vertical integration—because "[t]he antitrust laws . . . were enacted for the protection of competition not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977). Rather, Complaint Counsel must demonstrate that GRAIL's putative rivals would be foreclosed "in a substantial share" of a well-defined relevant product market, enabling Illumina to suppress innovation and output, and raise prices. *United States v. E.I. du Pont de Nemours & Co.*, 353

U.S. 586, 595 (1957); *see also Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 n.9 (2d Cir. 1979); *McWane Inc. v. FTC*, 783 F.3d 814, 838-39 (11th Cir. 2015).

ARGUMENT

Despite extensive discovery and a lengthy trial, Complaint Counsel fell short of meeting either its prima facie or ultimate burden of production and proof. Complaint Counsel's challenge to the Transaction lacks merit for multiple, independent reasons: (1) Complaint Counsel failed to prove the requisite antitrust markets; (2) Complaint Counsel failed to prove the Transaction is likely to substantially lessen competition; (3) Illumina's Open Offer eliminates any potential anticompetitive effects; (4) the Transaction will generate procompetitive efficiencies that more than offset the alleged harm; (5) the FTC's challenge to the reunion of Illumina and GRAIL violates the U.S. Constitution; and (6) the overwhelming weight of the evidence undermines Complaint Counsel's case, which is based on "evidence" that is inadmissible and/or deserving of no weight.

I. COMPLAINT COUNSEL FAILED TO PROVE THE REQUISITE ANTITRUST MARKETS.

To begin, Complaint Counsel's challenge to the Transaction must be rejected because Complaint Counsel failed to meet its burden on market definition. Complaint Counsel cannot prove either its relevant product market allegations or its related product market allegations. In the absence of such proof, Complaint Counsel's case founders at the outset.

A. Complaint Counsel Failed To Prove Its Alleged Relevant Market.

Defining the relevant market is a "necessary predicate" to finding a Clayton Act violation because the statute proscribes only mergers that "will substantially lessen competition within the area of effective competition." *E.I. du Pont de Nemours*, 353 U.S. at 593 (internal quotations omitted); *see United States v. Baker Hughes Inc.*, 908 F.2d 981, 982 (D.C. Cir. 1990)

(government must show "that a transaction will lead to undue concentration in the market for a particular product"). Defining a relevant market is necessary because the scope of the relevant market dictates the analysis of market power and a merger's potential anticompetitive effects. *See United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 181 (D.D.C. 2001).

Complaint Counsel "bears the burden of proof and persuasion in defining the relevant market." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 119 (D.D.C. 2004). If it is unable to carry that burden, then its case fails. *RAG-Stiftung*, 436 F. Supp. 3d at 291 ("Defining the relevant market is a necessary predicate to finding a Clayton Act violation because the proposed merger must be one which will substantially lessen competition within the area of effective competition.") (citations and quotations omitted); *see also Determined Prods. v. R. Dakin Co.*, 514 F. Supp. 645, 648 (N.D. Cal. 1979), *aff'd*, 649 F.2d 866 (9th Cir. 1981) ("Plaintiff must [] come forward with evidence of the relevant market. Failure to do so entitles defendant to judgment."). "Courts use two approaches to help define a relevant product market", the "hypothetical monopolist test" from the Horizontal Merger Guidelines, which "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 the candidate product market, or weighing of the *Brown Shoe* factors. *RAG-Stiftung*, 436 F. Supp. 3d at 293. With either test, "[t]he analysis begins by examining the most narrowly-defined product or group of products sold by the merging firms to ascertain if the evidence and data support the conclusion that this product or group of products constitutes a relevant market", and only if it does not does the analysis shift "to the next broadest product grouping to test whether that is a relevant market". *Arch Coal*, 329 F. Supp. 2d at 120.

Here, Complaint Counsel's alleged market fails for five, independent reasons: (1) it is impermissibly speculative and simultaneously over- and under-inclusive; (2) it disregards "reasonable interchangeability and cross-elasticity of demand"; (3) it runs counter to the Supreme Court's *Brown Shoe* factors; (4) it fails the Hypothetical Monopolist Test; and (5) it depends on Complaint Counsel's subjective and changing policy assessments, rather than established law and objective evidence. We address each in turn.

1. The Alleged Relevant Market Is Impermissibly Speculative and Simultaneously Over- and Under-Inclusive.

To meet its burden, Complaint Counsel was required to adduce admissible evidence proving its alleged relevant product market, not mere speculation. *See Reifert v. S. Cent. Wisconsin MLS Corp.*, 450 F.3d 312, 318 (7th Cir. 2006) ("a conclusory assumption of competition where products or services appear to be similar is insufficient" to prove a relevant product market); *Arch Coal*, 329 F. Supp. 2d at 116 (D.D.C. 2004) ("[A]ntitrust theory and speculation cannot trump facts").[1] It was also required to draw a market that was neither over- nor under-inclusive. *See Arch Coal*, 329 F. Supp. 2d at 120 (holding that the relevant product market was "no broader and no narrower than the SPRB coal" based on the "narrowest market" principle); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 58-60 (D.D.C. 2011) ("the relevant product market should ordinarily be defined as the smallest product market that will satisfy the hypothetical monopolist test."). Complaint Counsel fell far short: (a) its proposed market is impermissibly speculative because other than Galleri, it consists entirely of products

[1] *See also Golan v. Pingel Enter., Inc.*, 310 F.3d 1360, 1369 (Fed. Cir. 2002) (holding that the plaintiff "failed to provide sufficient evidence to establish a relevant market [because] . . . Golan offered only conclusory allegations" of the relevant market); *Am. Sales Co. v. AstraZeneca AB*, No. 10 CIV. 6062 PKC, 2011 WL 1465786, at *3 (S.D.N.Y. Apr. 14, 2011) ("limited, vague and conclusory" relevant market allegations "left [court] to speculate" whether relevant product market could be defined).

that are still in development, some in very early stages, and (b) its proposed market is simultaneously over- and under-inclusive, as it includes putative MCED tests that, if and when launched, will not be viewed by physicians or patients as substitutes for Galleri, and it excludes screening tests that use non-NGS technology.

a. The Alleged Relevant Market is Speculative.

[redacted]

This definition is speculative because, other than Galleri, it consists entirely of products that are still in development, some in very early stages. (PFF ¶ 680.1.) Those "products" have never been sold, and may never be sold. (PFF ¶ 680.2.) No one knows what features and functions they will have if they are sold, though it is clear that none will be like Galleri (50+ cancer types and accurate signal of origin detection) at any point in the foreseeable future. (PFF ¶ 680.3.) No one knows what cancers they might be shown to detect with adequate specificity and sensitivity. (PFF ¶ 680.4.) Unless aspiration is a substitute for evidence, there can be no credible claim that these "products" are substitutes for Galleri. (PFF ¶ 680.4.) Numerous fact witnesses testified that the future contours of the MCED field are largely speculative or unknown:

- [redacted]
- [redacted]

- Dr. William Cance, Chief Medical Officer of the American Cancer Society, said it "would be very hard to even speculate" on how long it will be before there is a blood-based test that's sensitive and specific enough to replace the standard of care cancer screens available today. (PFF ¶ 681.3.)

- Quest's Kristie Dolan testified that "the field is too nascent to say with any level of specificity" whether MCED tests would compete with each other in the absence of identical capabilities. (PFF ¶ 681.4.)

Because the proposed market does not exist, Complaint Counsel's economic expert, Dr. Scott Morton, admitted that she did not and could not consider any real world evidence regarding the pricing of MCED tests:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- "Q. In forming your opinions, is it accurate to say that you did not consider data describing the past purchase patterns of consumers in their responses to price changes for MCED tests? A. As I have said, the MCED test was only launched a couple of months ago. We don't really have a setting in which consumers can do anything except buy Galleri in an uninsured fashion." (PFF ¶ 682.5.)

[redacted] She did not attempt to fill the information gaps—using surveys or other means—to assess customers' likely

preferences and switching behavior regarding the products in her proposed MCED market or regarding those products she excludes. (PFF ¶ 683.1.) And she did not at all attempt to analyze likely substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. (PFF ¶ 683.2.)

Moreover, the overwhelming evidence showed that customers are unlikely to view the products in development as substitutes with Galleri. (PFF ¶ 684.) None of the tests in development has demonstrated the capability to detect 50 cancer types—or any number close to what GRAIL has been able to demonstrate. (PFF ¶ 684.1.) Nor has any test in development demonstrated the ability to identify the cancer signal of origin without the aid of a whole-body PET-CT scan.[2] (PFF ¶ 684.2.) [redacted] Determining the boundaries of Complaint Counsel's alleged market depends on a comparison to, or of, one or more non-existent tests. (PFF ¶ 684.3.) The inclusion of these undeveloped tests in the supposed relevant market is thus conjectural. (*See* PFF ¶ 685 ("The timing of when [putative MCED developers are] going to actually have commercial products and when they're going to launch them and ultimately when [they are] going to get insurance coverage so that they have a chance of significant competitive success, . . . is highly uncertain and it's in the future.").)

While courts have interpreted the language in Section 7 to infer that Congress's "concern was with probabilities, not certainties," that language was "intended to allow courts to appreciate immediately the potential consequences that a particular acquisition might have upon

[2] A PET-CT scan is a form of imaging technology that is not recommended for early cancer screening due to its additional cost and potential to expose patients to radiation. (PFF ¶¶ 149, 152–152.2.)

an *existing line of commerce*." *SCM Corp. v Xerox Corp.*, 645 F.2d 1195, 1211 (2d. Cir. 1981) (citing *Brown Shoe*, 370 U.S. at 323) (emphasis added). Thus, it is "[t]he existing market [which] provides the framework in which the probability and extent of an adverse impact upon competition may be measured." *SCM Corp.*, 645 F.2d at 1211. Complaint Counsel may not—as it does here—rely exclusively on speculation about future markets to support its alleged antitrust market. *Arch Coal*, 329 F. Supp. 2d at 116–17. Complaint Counsel's focus on speculative, future possibilities, rather than actual facts about the market in which Galleri is sold, is a sleight of hand without support in the case law.

The fact that the hypothesized MCED market proposed by Complaint Counsel does not, in fact, exist is significant because courts have held that where a market does not exist, there can be no anticompetitive effects. *Kenney v. Am. Bd. of Internal Med.*, 412 F. Supp. 3d 530, 548 (E.D. Pa. 2019), *aff'd*, 847 F. App'x 137 (3d Cir. 2021) (holding that Defendant "cannot have a monopoly in a market that does not exist."); *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 480 (7th Cir. 1988) ("It is impossible to monopolize a market that does not exist."); *Siva v. Am. Bd. of Radiology*, 418 F. Supp. 3d 264, 277 (N.D. Ill. 2019) (holding that a defendant cannot have or exploit a "monopoly in a market that does not exist"); *In re Altria Grp., Inc.*, No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted.").

Courts have repeatedly rejected alleged markets defined to include products that are not yet in existence and whose features are highly uncertain, and have rejected the inclusion of undefined future products in a relevant market. *See SCM Corp.*, 645 F.2d at 1211 (overturning jury verdict in plaintiffs' favor and holding that patent acquisitions did not violate

Section 7 as a matter of law because the relevant product market did not exist at the time of the acquisitions and for another eight years following the acquisitions); *Fraser v. Major League Soccer, L.L.C.*, 97 F. Supp. 2d 130, 140 (D. Mass. 2000), *aff'd*, 284 F.3d 47 (1st Cir. 2002) ("The relevant test under § 7 looks to whether competition in *existing* markets has been reduced. Where there is no existing market, there can be no reduction in the level of competition. . . . Competition that does not exist cannot be decreased."); *Epic Games, Inc. v. Apple Inc.*, 2021 WL 4128925 at *56 (N.D. Cal. 2021) (excluding the offerings of certain gaming companies from the relevant product submarket because the record was limited as to those companies, and they were "too new for a determination of whether they should or should not be included in the relevant product market"); *Apartment Source of Pa., L.P. v. Phila. Newspapers, Inc.*, No. CIV. A. 98-5472, 1999 WL 349938, at *22–24 (E.D. Pa. May 21, 1999) (finding in defendants' favor because plaintiffs' alleged market was at most an "emerging submarket" within an apparent broader market and was not a well-defined separate market); *Crucible, Inc. v. Stora Kopparbergs Bergslags AB*, 701 F. Supp 1157, 1161 (W.D. Pa. 1988) ("Regarding the 1966 acquisition of the Battelle patents, a finding of no relevant market in PM high speed steel products is mandated by the fact that commercial production and marketing of PM high speed steel products in the United States did not begin until 1971, four years after the patent acquisitions.").[3]

[3] Moreover, the fact that "courts have long applied antitrust laws to firms that have not yet entered or do not yet have sales in the relevant markets" (CC Pretrial Br. at 31) is no help to Complaint Counsel here. In those cases, courts blocked acquisitions between an incumbent firm and a potential competitor that demonstrated concrete plans to enter a mature, well-defined and—perhaps most critically—undisputed product market; none holds that products in early stage development should be considered part of a relevant product market. For example, the court in *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208 (11th Cir. 2012), held that the acquired firm, Microporous, was an actual, rather than potential, competitor to Polypore in the SLI separator

Where plaintiffs have tried to define a market based on speculative future products, courts have instead opted to define the market based on existing products. *Apartment Source* is illustrative. In *Apartment Source*, plaintiffs provided apartment location services, which were essentially liaison services seeking to connect consumers looking for apartments with apartment providers. 1999 WL 349938, at *1. Defendants owned the major Philadelphia newspapers as well as a competing apartment location services company. *Id.* Defendants refused to allow plaintiffs to advertise their apartment location services in defendants' newspapers, and plaintiffs asserted the refusal was a violation of the Sherman Act. *Id.* Plaintiffs alleged that the relevant product market was the market for apartment location services, but the court rejected the proposed product market as impermissibly speculative. *Id.* at *22–23. The court stated that:

> To the extent that it can be argued that an [apartment location services] market exists at all in the Philadelphia Region, it is at most an emerging submarket within the broader, more readily apparent market for apartment rentals. As such, it has not yet fully emerged as a defined product market in the eyes of apartment communities, the consumers. Only a well-defined submarket can constitute a relevant market. An emerging submarket that has not yet developed into a distinct and identifiable market by definition is not well-defined, and therefore does not constitute a relevant product market under Section 2 of the Sherman Act. In other

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market based on its conduct and preparations to enter that market. 686 F.3d at 1214–15. There was no dispute as to the definition and contours of the SLI separator market. *Id*. Similarly, in *FTC v. Procter & Gamble Co.*, the Supreme Court held that a merger between Procter & Gamble and Clorox would eliminate potential competition of Procter & Gamble in the agreed-upon market for household liquid bleach. 386 U.S. 568, 571, 580–81 (1967). Complaint Counsel also cited *United States v. General Dynamics Corp.*, 415 U.S. 486, 501 (1974), for the proposition that "[e]vidence of past production does not, as a matter of logic, necessarily give a proper picture of a company's future ability to compete." (CC Pretrial Br. at 31.) The case plainly does not support Complaint Counsel's theory (and it is not apparent why Complaint Counsel believes it does): *General Dynamics* held that the vagaries of the coal production market are such that evidence of past market share is not as relevant a predictor of future strength as it would be in most markets. *Id.* Nothing in the decision supports including in a relevant product market undefined products that are years from existence.

> words, the Court must determine whether an ALS market or submarket currently exists in the Philadelphia Region. The fact that an ALS market may exist in the Philadelphia Region in the future is irrelevant. The definition of the relevant market must be based on the market existing at the time of the alleged Section 2 offense, not on a market that might possibly exist in the future.

Id. at *24. For the same reason, this Court should reject Complaint Counsel's proposed market as impermissibly speculative.

b. The Proposed Market Is Simultaneously Over- and Under-Inclusive

In addition to being impermissibly speculative, Complaint Counsel's proposed market is over-inclusive. It includes any test that purports to detect more than one cancer type, despite the fact that such a definition would include tests that are capable of detecting only two or three cancer types and that would plainly be no substitute for Galleri, which has been shown to detect more than 50 cancer types. [redacted] The absurdity of Complaint Counsel's market definition is illustrated by the fact that it draws a seemingly illogical line between single- and two-cancer tests: a test capable of detecting only two or three cancers is a closer substitute for the single-cancer tests that Complaint Counsel properly excludes from the relevant market, than it is to a test for 50 cancer types. (PFF ¶ 687 (RX6004 (Katz Trial Dep. at 30) ("[I]t's counterintuitive that a test, say, for testicular cancer should be out of the market because it's not a close enough substitute to a test that [detects] testicular cancer *and* prostate cancer" but that two hypothetical tests that detect "two completely nonoverlapping" cancer types are included "because they each do two").)

In addition to clearly not being substitutes for *Galleri*, many of the tests in Complaint Counsel's proposed market are also not even substitutes for *each other*. (PFF ¶ 688.)

Complaint Counsel's proposed market would include any test that screens for two or more cancer types, even though that would necessarily group together screening tests that detect distinct cancer types in different populations. (PFF ¶ 689.) For example, as Dr. Katz testified: "suppose we have two tests, one of which covers testicular cancer and prostate cancer . . . and then we have another one that does uterine cancer and ovarian cancer. It's really difficult for me to see how those could be substitutes for one another. I believe they're not. And I think that shows a fundamental defect in [Complaint Counsel's proposed] market." (PFF ¶ 690.)

By defining the market to include tests that cannot be shown to be substitutes for Galleri or each other, Complaint Counsel's proposed market violates the narrowest market rule. *See Arch Coal, Inc.*, 329 F. Supp. 2d at 120 ("Relevant market analysis is based on the 'narrowest market' principle", the analysis of which requires "examining the most narrowly-defined product or group of products sold . . . [that] constitutes a relevant market"); (*see also* PFF ¶ 690.1 (Dr. Scott Morton "did not attempt to define the narrowest relevant market . . . that would pass the hypothetical [monopolist] test, and I believe this is a fact, that she did not explain or offer a justification for why that would be appropriate. And that's not something that's relying on testimony by other people. It's a failure of the logic and the form of analysis that she's applied.").)

At the same time, Complaint Counsel's proposed market is also under-inclusive, because it excludes MCED tests that are not based on NGS technology. (PFF ¶ 690.) It is undisputed that there are at least two MCED tests on the market that are not based on NGS technology, including StageZero's Aristotle test,[4] a microarray-based liquid biopsy test that

[4] [redacted]

interrogates mRNA to detect 10 cancer types, and Genesys Biolabs' OneTest, a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (PFF ¶¶ 692.1–692.2.) Complaint Counsel offers no basis for excluding these tests, which are currently on the market, from its proposed relevant market. *See Sungard Data Sys*, 172 F. Supp. 2d at 193 ("[T]he Court cannot accept the government's overly narrow and static definition of the product market."); *State of N.Y. v. Kraft Gen. Foods, Inc.*, 926 F. Supp. 321, 361 (S.D.N.Y. 1995) (rejecting plaintiff's more narrowly defined "adult cereal" market, finding "no principled basis for defining the relevant product market more narrowly than all [ready-to-eat] cereals").

Moreover, a number of companies are developing cancer screening tests that are not based on NGS technology, including tests in development from InterVenn Biosciences, PrognomiQ, and Somalogic. (PFF ¶ 693.) These tests are too early in the development timeline to be included in a relevant market with Galleri. (PFF ¶ 693.1.) But if there were any merit to Complaint Counsel's approach to market definition (which sweeps in numerous tests that are in the early stages of development and plainly not substitutes for Galleri), then there is no reason to exclude tests from InterVenn, PrognomiQ, and Somalogic. There is no evidence, or reason to believe, that an MCED test must use NGS technology. (PFF ¶ 694.) Nor is there any evidence, or reason to believe, that customers (*i.e.*, patients, health care professionals and payors) have any preference for an MCED test based on the platform used to run it. (PFF ¶ 695.) What customers care about is whether a test works and for which indications, not how exactly it works. (PFF ¶ 696); *see, e.g.*, *Apartment Source*, 1999 WL 349938, at *23 ("Even though the means used by these apartment communities to secure renters may not be identical substitutes for one another, they serve the same function and are used interchangeably"); *Telerate Systems, Inc. v. Caro*, 689

F. Supp. 221, 237-38 (S.D.N.Y. 1988) ("The first issue [of reasonable interchangeability] is "functional interchangeability"—the degree to which various products are able to perform the same *functions*") (emphasis added).

2. The Alleged Market Includes Products in Development That Are Not Reasonably Interchangeable.

In addition to the fact that Complaint Counsel's proposed relevant market is impermissibly speculative and both over- and under-inclusive, it comes nowhere close to satisfying the test of reasonable interchangeability.

A relevant product market consists of "products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325; *see du Pont*, 351 U.S. at 395. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function." *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered).

"Interchangeability of use and cross-elasticity of demand look to the availability of products that are similar in character or use to the product in question and the degree to which buyers are willing to substitute those similar products for the product." *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 157 (D.D.C. 2000). "The first principle of market definition is substitutability: a relevant product market must 'identify a set of products that are reasonably

interchangeable[.]'". *ProMedica Health Sys. v. FTC*, 749 F.3d 559, 565 (6th Cir. 2014) (quoting Horizontal Merger Guidelines § 4.1). "Chevrolets and Fords might be interchangeable in this sense, but Chevrolets and Lamborghinis are probably not." *Id.* (citing 2B Phillip E. Areeda, Herbert Hovenkamp & John L. Solow, Antitrust Law ¶ 533e at 259 (3d ed. 2007)). "The general question is whether two products can be used for the same purpose, and if so, whether and to what extent purchasers are willing to substitute one for the other." *Arch Coal*, 329 F. Supp. 2d at 119 (quotations omitted).

Not on the Market. At present, there is no product in existence that is reasonably interchangeable with GRAIL's Galleri test. (PFF ¶ 697.) Galleri is the only multi-cancer early detection test on the market testing for anywhere near 50 cancer types. (PFF ¶ 698.) The prices and qualities of any other yet-to-exist products are not even specified. (PFF ¶ 699.)

Years Away. Most of the putative MCED developers identified by Complaint Counsel do not expect (and none can reasonably be expected) to launch a screening test for more than one cancer type for many years. (PFF ¶ 700.)[5] This is because developing a cancer screening test that can detect more than one type of cancer is challenging and requires many years of research, development and clinical validation. (PFF ¶¶ 294–95, 310–11.) [redacted]

[redacted]

[5] *See, e.g., U.S. v. Microsoft Corp.*, 253 F.3d 34, 53-4 (D.C. Cir. 2001) (excluding middleware from the relevant market because "[w]hatever middleware's ultimate potential . . . consumers could not *now* abandon their operating systems and switch to middleware") (emphasis added); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc*, 433 F. App'x 598, 599 (9th Cir. 2011) ("The failure to allege a product market consisting of reasonably interchangeable goods renders the [complaint] 'facially unsustainable'").

[redacted]

First, a test developer must undertake sample collection, research and biomarker discovery. (PFF ¶ 303.) According to Dr. Cote, biomarker discovery can take anywhere from 18 months to three years, and in some cases much longer. (PFF ¶ 306.5.) To perform biomarker discovery, samples must be collected for each of the cancer types a test developer wishes to detect. (PFF ¶ 304.) Samples must be collected uniformly to ensure high quality samples that are comparable. (PFF ¶ 304.1.) The FDA has said that, [redacted] Biomarker discovery involves efforts by the test developer to identify which biomarkers are the best at predicting that an individual has cancer and to determine if a biomarker may be used to distinguish between an individual who has cancer and an individual who does not. (PFF ¶ 306.)

Scientists have not discovered any biomarkers that are "pan cancer" (PFF ¶ 308), so even though companies may chance upon one or a few relevant biomarkers for the new cancer

type during development of their previous cancer screening test, full biomarker discovery would still be required to identify a panel of biomarkers for the new cancer type(s) to ensure the accuracy, specificity and sensitivity of that multi-cancer screening test. (PFF ¶ 309.) The challenge is multiplied as the number of cancers under consideration to be screened increases. (PFF ¶ 309.1.) As Gary Gao of Singlera explained, in ten years, Singlera has only had "enough sample type[s] for five given types of a cancer to validate . . . there are hundreds of different cancer types, and over a ten-year span, you can only collect enough sample for four or five different cancers for validation purpose. So for five different kinds that we can estimate, you know, it may take seven to eight years [to conduct a] prospective trial to have FDA approval. ***For 50 or 100 kinds of cancer, it would take maybe 50 years***." (PFF ¶ 309.2.)

Second, after selecting the biomarkers for the assay, a test developer enters the "development" stage and focuses on optimizing the assay across different metrics, including costs, quality control and other performance characteristics. (PFF ¶ 310.) The test developer must also build its data analysis and interpretation software, often using artificial intelligence, to catalogue the biomarkers analyzed in the sample to report a result. (*See* PFF ¶¶ 339, 346, 366.)

Third, after completing the initial research and development steps, test developers must clinically validate their test, to ensure its efficacy in detecting cancer and to identify the cancers that the test is intended to detect at an early stage. (PFF ¶ 311.) During this stage—as well as in the earlier development stages—a test developer will conduct the following studies:

- Retrospective, case-control studies involve the use of pre-collected samples from a cohort of patients diagnosed with the target cancer or cancers and a cohort of healthy patients. (PFF ¶ 315.1.) These studies are often used as validation studies, which are conducted to understand variation in the data generated under specific laboratory conditions. (PFF ¶ 315.5.) Validation helps define the scope or range of conditions under which reliable results may be obtained. (PFF ¶ 315.5.)

- Prospective, observational studies involve the collection of samples from patients who are asymptomatic and then follow these patients for a period of time to see who develops cancer. (PFF ¶ 316.) A study is "observational" where the investigator will not act upon study participants, such that a physician overseeing the patient will not be informed of any test results at least until after the study is over. (PFF ¶ 316.1.)

- Prospective, interventional studies involve the prospective collection of samples from asymptomatic patients where the investigator intercedes as part of the study design—that is, on a positive finding in a cancer screening study, the physician overseeing the patient will be informed, and is likely to order follow-up tests to rule in or out cancer, and then corresponding treatments if the patient is diagnosed with cancer. (PFF ¶ 317.)

The types of studies a test developer will conduct to validate a test depends, in part, on the format they intend to use when they launch the test. A company can offer a clinical test to patients in three ways: as a Laboratory Developed Test ("LDT"), as a single-site IVD test, or a distributed (also called "kitted") IVD. (PFF ¶ 187.) Single-site and distributed IVDs require FDA approval, while LDTs must meet lesser, but still rigorous, quality and safety standards for clinical diagnostic testing. (PFF ¶¶ 187.1.1–187.3.) To obtain FDA approval, a cancer screening test developer would need to conduct a large, prospective, interventional study in asymptomatic patients. (PFF ¶¶ 318–24.) Between planning, recruiting participants at multiple sites, testing and analyzing samples, diagnostic follow-up, further therapeutic intervention, and multiple additional follow ups, such a trial will take between 5 and 7 years. (PFF ¶¶ 324.)

Galleri has achieved many of these development milestones, having launched as an LDT in June 2021. (PFF ¶ 341.) Prior to launch, however, GRAIL undertook a rigorous five-year development process, involving four clinical studies with a combined total of nearly 140,000 participants in North America and the United Kingdom. (PFF ¶¶ 295.1, 368–368.1.) First, GRAIL undertook its Circulating Cell-free Genome Atlas (CCGA) study, a prospective, observational study in which GRAIL discovered and catalogued genetic mutations responsible for cancer by tumor tissue sequencing and analyses across multiple technology platforms— *i.e.*,

an "Atlas" of cancer signals. (PFF ¶¶ 374–79.) Doing so was no small task. CCGA involved 15,254 participants from 142 trial sites in the U.S. & Canada. (PFF ¶¶ 371.) Conducting the study across such a high number of trial sites was crucial to detect a large number (*i.e.*, over 50 types) of cancers. (PFF ¶¶ 371.1.) For cancers with no current standard of care screening test, it was not possible for GRAIL to collect samples from existing testing sites as could be done for breast or colorectal cancers. (PFF ¶¶ 371.1.) Collecting a sufficient number of samples of early stage and rarer cancers was difficult and time-consuming, especially because samples had to be collected in a uniform manner to ensure clinical rigor and quality. (PFF ¶¶ 371.1.) The effort was "unprecedented in scale and complexity and cost", as GRAIL's clinical operations team had to go to multiple sites just to collect a sufficient number of samples of these rare cancers. (PFF ¶¶ 371.1.)

Based on the results of the first part of CCGA, GRAIL determined that interrogating methylation patterns in the genome was the best approach for both detecting the presence of cancer and localizing that cancer in the body. (PFF ¶¶ 382–83.) Methylation is a biological process that affect how cells behave—in the context of cancer, methylation tends to "turn off" tumor-suppressing genes and "turn on" tumor-promoting genes. (PFF ¶ 345.1.) To make sense of these patterns, GRAIL used the samples it had collected—across 50+ cancer types at all stages—to look at over a million methylation sites in the genome and train a machine learning algorithm to distinguish a cancer signal from a noncancer signal. (PFF ¶¶ 346–46.1.) If a cancer signal gets detected, the patterns are then analyzed through another classifier, which looks and weighs different features from these patterns to predict where the cancer signal came from in the body. (PFF ¶ 346.1.)

In addition to CCGA, Galleri is in the midst of conducting three additional studies: STRIVE, a prospective, observational study assessing Galleri's performance in approximately 100,000 women undergoing mammography (PFF ¶¶ 403–04); SUMMIT, a prospective, observational study to evaluate Galleri's performance in a 13,000-participant population at high risk for lung cancer (PFF ¶¶ 407–09); and PATHFINDER, a 6,662-participant prospective interventional trial in which Galleri results were returned to participants and their clinicians to allow them to undertake the necessary diagnostic steps necessary for a proper cancer diagnosis (PFF ¶¶ 394–99.)

Accounting for all of these steps in the development process, Dr. Cote opined that most of the putative MCED developers identified by Complaint Counsel were at least five to seven years away from launching any kind of MCED test. (PFF ¶ 707.3.) The putative MCED test developers' own testimony is consistent with this timeline and also shows that none of them have come close to replicating GRAIL's development efforts:

- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- Singlera. Singlera is "far, far away" from launching its PanSeer test. (PFF ¶ 706.) Singlera does not plan on marketing its PanSeer test in the US until it has received FDA approval. (PFF ¶ 706.1.) Singlera is not currently in talks with the FDA. (PFF ¶ 706.2.) It will "take at least seven to ten years of time for [the current PanSeer] test to be able to go to the FDA". (PFF ¶ 706.3.)

- Exact/Thrive. Although Thrive had published studies of the performance of CancerSEEK prior to being acquired by Exact, Exact has since said it is going back to the drawing board with the test and "combining the Exact Sciences and Thrive approaches in one test." (PFF ¶ 726.6.) [redacted]

These far-off projections demonstrate that many years of development are required to develop an MCED test anywhere comparable to Galleri. (PFF ¶ 707.) And, as Dr. Aravanis explained, starting with a single-cancer test does not accelerate the development timeline for a multi-cancer test, because for each cancer included in a multi-cancer test, you "have to go through a somewhat similar process to what GRAIL did", meaning "a research phase", "a test development phase", and "a clinical phase", and that must be done "for each cancer", which, if done "serially" would take a "very long time" and is "not practical". (PFF ¶ 707.1.) As Dr. Chahine of Helio Health testified, compared to the R&D process for a single-cancer screening test, "[i]t probably gets exponentially harder if you're adding . . . five and ten cancers, and so just from a practical standpoint, a small company trying to go after multiple cancers at the same time I think is just really just not feasible." (PFF ¶ 707.2.) Complaint Counsel's proposed market should fail on this basis alone, because it has not shown that any putative MCED test will "enter the market in a relatively short time . . . to constrain [Galleri's] pricing in the reasonably foreseeable future". *Microsoft*, 253 F.3d 34 at 53–54. Where the hypothetical products at issue will take five to seven—or possibly ten—years to develop, "to conclude that future products would likely . . . reach the market would require unacceptable and unfair speculation." *In re Altria Grp., Inc.*, FTC No. 9393, at 108–09 (Feb. 15, 2022).

No proof of interchangeability. Even if the tests in development were on the market, or could be expected to launch in the near term, Complaint Counsel failed to prove that any of these tests will be reasonably interchangeable with Galleri if and when they are launched. (PFF ¶ 708.) The purchasers of any MCED test will be patients, health care providers and/or insurers. (PFF ¶ 708.1.) Complaint Counsel did not call any medical expert, nor a single patient, health care provider or insurer to testify that they would substitute one of the tests in development (were it ever to be sold) for Galleri. (PFF ¶ 708.2.) Nor did Complaint Counsel conduct any surveys of such groups (PFF ¶ 708.3 (Complaint Counsel's expert "didn't attempt to fill those information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior.")—although such surveys are routinely done in healthcare markets. *See, e.g.*, *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 982-83 (N.D. Iowa 1995) (agreeing with defendants' relevant market based on survey results of patient preferences). Complaint Counsel also did not attempt to show the likely price of these tests. (PFF ¶¶ 750.1–750.4.) These are fatal flaws, especially where Complaint Counsel had ample power and authority to produce such a witness if there were any favorable to its case. *See Boardman v. Nat'l Med. Enters.*, 106 F.3d 840, 844 (8th Cir. 1997) ("Drawing an adverse inference from the failure of a party to put on key witnesses relevant to some issue is most reasonable when it is the party with the burden of proof on that issue who fails to do so."); *Streber v. Comm'r*, 138 F.3d 216, 221–22 (5th Cir. 1998) ("In general, a court may draw a negative inference from a party's failure to produce a witness "whose testimony would elucidate the transaction.") (citation and quotations omitted); *United States v. Lowe*, 234 F.2d 919, 923 (3d Cir. 1956) ("The rule is well

known that as a general proposition when one fails to call a witness who might have something relevant to say about his case an unfavorable inference can be urged against the one who fails to call him.").

Ample proof of no interchangeability. Although Respondents do not bear the burden of proof as to market definition, they called, and the Court heard testimony from, numerous witnesses demonstrating that Galleri is not reasonably interchangeable with the putative MCED tests in development, which (once launched) will screen for fewer cancer types and do not have the ability to detect cancer signal of origin with a single blood draw as does Galleri. (PFF ¶ 709.) For example:

- Francis deSouza, Illumina's CEO, testified, based on his conversations with doctors during due diligence for the Transaction, that Galleri would not compete with tests that screen for fewer than ten cancers or with tests that do not identify cancer signal of origin. (PFF ¶ 709.1.) ("[D]octors who are looking for 50 cancers and doing a screen would not want a test that did not tell the patient where that cancer was. They felt that that [it]would [not work] to raise so much anxiety in a person without telling them what they actually have. And so for that use case, for doing screening of a healthy person to identify if they have 50 cancers, they felt it was essential that as part of the conversation with the patient you're immediately able to say what to do next, you know, look at this organ, image your pancreas or something . . . and so they would not substitute Galleri with another test that identified 50 cancers but didn't tell you what cancer it was and where it was, and so they are not substitutes."))

- Illumina's Chief Technology Officer (and GRAIL's former Chief Science Officer and Head of R&D), Alex Aravanis, testified that it is "unlikely" Galleri will compete with a test that screens for fewer than ten cancers and that Galleri would not compete with a test that does not identify cancer signal of origin, since it would be used in a very different clinical context than Galleri. (PFF ¶ 709.2.)

- GRAIL's then-CEO, Hans Bishop, testified that he did not foresee Galleri competing with other MCED developers, such as Guardant, Freenome, Exact/Thrive and Singlera, given the substantial differences between the tests those companies may be developing and Galleri. (PFF ¶ 709.3.)

- Dr. Josh Ofman, Grail's Chief Medical Officer, testified that Galleri 'will not compete with MCED tests that are first pursuing colon cancer tests: "[w]e screen for colon cancer with stool-based colon cancer screening tests or colonoscopy, which is the gold standard, and so . . . for people who want to use blood to look for colon cancer, they'll just do that. But adding a multicancer early detection test to the

single-cancer screening test is a very different activity. They're not really competing." (Ofman, Tr. 3310-11.) Dr. Ofman also testified that Galleri would not compete with a test that detected two or three cancers, because "conceptually what you're trying to do with Galleri is very different than something you'd be trying to do with a test that says we can find stomach and esophageal cancer." (PFF ¶ 709.4.)

- [redacted]
- [redacted]

The intuition as to complementarity between a 50-cancer test and a test that screens for fewer cancers was also supported by some of Complaint Counsel's third-party witnesses. (PFF ¶ 710.) [redacted] In response to questioning about what customers will view PanSeer and Galleri as substitutable options, Singlera's Chairman Gary Gao testified that "I don't think there is a product yet. And I could not say how we are interchangeable right now . . . ." (PFF ¶ 710.3.)

Complaint Counsel has no testimony from potential consumers of MCED tests. (PFF ¶ 711.) The only testimony that Complaint Counsel elicited regarding substitutability is self-serving testimony from certain putative MCED test developers that they view GRAIL as a rival and hope that the tests they are working on will one day compete with Galleri. (PFF ¶ 712.)

They also point to certain Illumina, GRAIL and third-party documents that identify competitors or potential competitors to GRAIL and Galleri in the future. However, "the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes"; rather, market definition hinges on whether *consumers* view the products as reasonable substitutes. *FTC v. Sysco Corp*., 113 F. Supp. 3d 1, 26 (D.D.C. 2015) (emphasis added) (citations omitted); *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009) (holding that lay testimony and internal marketing documents "do[] not provide a sound economic basis for assessing the market . . . the way that a proper interchangeability test would"); *FTC v. Lundbeck, Inc.*, No. CIV. 08-6379 JNE/JJG, 2010 WL 3810015, at *20 (D. Minn. Aug. 31, 2010), *aff'd,* 650 F.3d 1236 (8th Cir. 2011) (rejecting FTC's proposed market definition consisting of both NeoProfen and Indocin IV despite internal company documents that refer to a market that consists of NeoProfen and Indocin IV); *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 498 (2d Cir. 2004) (finding that generic warfarin sodium alone constituted the relevant market even though "the industry undoubtedly acknowledges that Coumadin competes to some extent with generics").

3. Complaint Counsel's Alleged Market Runs Counter to the Supreme Court's *Brown Shoe* Factors.

In addition to interchangeability of use and cross-elasticity of demand, courts look to the "practical indicia" set forth in *Brown Shoe* as guides for defining the relevant market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (examining "such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors"). The *Brown Shoe* factors "are not to be

used in a 'talismanic fashion' whereby their presence or absence are regarded as mechanically dispositive of the issue." *Kaplan v. Burroughs Corp.*, 611 F.2d 286, 292 (9th Cir. 1979) (citation omitted). Rather, they must be applied "pragmatically" to determine the existence of the "economically significant" product market. *Id.* (citations omitted).

As discussed in Sections I.A.1–I.A.2 *supra*, Complaint Counsel has not adduced sufficient evidence to define its preferred relevant market. To the extent there is sufficient record evidence to properly apply the *Brown Shoe* practical indicia, they point to a relevant product market consisting only of Galleri, not Galleri and a number of uncertain and unfinished potential tests in development that lack, and cannot plausibly develop in the foreseeable future, the distinctive features of Galleri. *See Microsoft*, 253 F.3d at 53–54 (stating that the test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function"); *Epic Games, Inc. v. Apple Inc.*, No. 4:20-CV-05640-YGR, 2021 WL 4128925, at *56 (N.D. Cal. Sept. 10, 2021) (excluding Nintendo and other gaming services from the market because they were "too new" to determine "whether consume[r]s will or do consider these products reasonably interchangeable").

a. No industry or public recognition of the alleged market as a separate economic entity

The "industry or public recognition" factor is one that concerns "observations about what one ordinarily observes when a market is distinct" and "matters because we assume that economic actors usually have accurate perceptions of economic realities." *Rothery*, 792

F.2d at 218 n.4. Neither the industry nor the public recognizes an MCED market *as defined by Complaint Counsel*.

To be sure, there is an NGS-based multi-cancer early detection test available for sale in the U.S. (Galleri), and a number of companies are working to develop cancer screening tests, some of which have been loosely described as MCED tests. (PFF ¶¶ 698, 701–706.) But there is no industry or public recognition of a separate "economic entity" comprising any NGS-based screening test that detects more than one cancer type.

As stated, Galleri is the only test on the market that has been shown (with published data) to detect more than 50 cancer types and cancer signal of origin. (PFF ¶ 715.1.) By contrast, none of the purported MCED tests in development that Complaint Counsel cites has had a single sale. (PFF ¶ 715.2.) None has been shown (with published data or otherwise) to detect more than 10 cancers (and most far fewer). (PFF ¶ 715.3.) And none has the ability to detect cancer signal of origin. (PFF ¶ 715.3.) Most of the in-development tests are focused at present solely on detecting a single cancer with the aspiration of one day detecting more cancers by adding additional biomarkers and conducting additional clinical trials. (PFF ¶ 715.4.)

The available industry or public information about the putative MCED tests in development does not suggest that these tests belong in the same product market as Galleri. Instead, they make clear that they are all very different from Galleri. Analyst reports from investment banks that cover the broader biotechnology space recognize that Galleri is very different. (PFF ¶ 717.) For instance, a report on the liquid biopsy space from Cowen notes that GRAIL has "conducted systematic clinical studies" and that Galleri "has been shown to be capable of identifying >50 types of cancers by scanning methylation patterns". (PFF ¶ 717.1.) The only other entity it recognizes as pursuing a multicancer screening test is Thrive, but notes

that it had only been shown to detect 10 cancer types and required the use of a confirmatory PET-CT scan. (PFF ¶ 717.1.1.)

The report notes that Freenome and Guardant are among the companies in a *separate market segment* pursuing single-cancer screening tests to detect colorectal cancer, lists Singlera in passing under the heading "[s]ome [o]thers" following its summary of the colorectal cancer screening market, and considers Helio in a separate segment for "High Risk Cancer Detection" for its liver cancer screening test. (PFF ¶ 717.1.2.) Cowen does not recognize [redacted] as pursuing early cancer detection at all: it notes [redacted] as a participant in the recurrence monitoring/MRD and "liquid biopsy for biopharma" (*i.e.*, companion diagnostic) segments, and [redacted] in the therapy selection and "liquid biopsy for biopharma" market segments. (PFF ¶ 717.1.3.)

An analyst note from SVBLeerink comes to a similar conclusion, only mentioning GRAIL and Thrive as pursuing "multi-cancer detection" and noting that Guardant and Freenome are among those in the colorectal cancer screening space. (PFF ¶ 717.2.) SVBLeerink also notes a number of "must have" features for a multi-cancer screening assay, including cancer signal of origin capability (which it notes as "essential"); "99%+ specificity"; detection of "higher mortality cancers with no current screening methodologies"; "and [l]arge-scale, prospective trials that reflect prevalence of cancer in the real world". (PFF ¶ 717.2.1.)

Only Galleri has each of these features. (PFF ¶¶ 61–62, 355, 400–01.) Illumina also recognized this, and its internal documents show that, much like the broader industry, it believes that Galleri is highly differentiated. (PFF ¶ 718.) [redacted]

[redacted]

In addition to analyst reports and internal documents, the features and functions of Galleri are also described in detail in several peer-reviewed publications, including *Annals of Oncology*, and GRAIL has multiple clinical trials listed at clinicialtrials.gov. (PFF ¶ 719.) These peer-reviewed publications have not recognized an "MCED" market as Complaint Counsel would wish to define it. Rather, the available peer-reviewed publications show, with only two exceptions, that Complaint Counsel's so-called "MCED" developers have only published peer-reviewed articles or initiated clinical trials, if any, for single-cancer screening tests. (PFF ¶ 719.1.) Some have not even initiated clinical trials relating to asymptomatic cancer screening at all, even early stage case-control trials, let alone published articles. (PFF ¶ 720.)

Other than Galleri, of the developers that Complaint Counsel relies on, only Exact/Thrive and Singlera have conducted clinical trials and/or published one or more peer-reviewed articles about their purported MCED tests in development. (PFF ¶ 721.) But the data from those trials shows that these tests are very different from Galleri. (PFF ¶ 721.) The Exact/Thrive data show only that its CancerSEEK assay can detect, at most, 10 types of cancer—with no identification of tissue of origin (a whole-body PET-CT scan is required to identify the tissue of origin for every positive case). (PFF ¶ 721.1.) [redacted]

Similarly, the published Singlera data is from a 418-sample—astonishingly few compared to the hundreds of thousands of participants in GRAIL's trial—case control study and shows only that Singlera's PanSeer assay detected five types of cancer. (PFF ¶ 721.3.) Moreover, the data show that PanSeer achieved only 96.1% specificity, [redacted] (PFF ¶ 721.4.)

Courts have declined to recognize a proposed market as a separate economic entity in cases where there was greater industry or public recognition than there is here. *See, e.g., Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 614–16 (8th Cir. 2011) (declining to recognize the hospital's proposed market despite evidence of industry recognition from hospital documents, statements by other industry executives and contracts); *Ky. Speedway*, 588 F.3d at 919 (holding that lay testimony and internal marketing documents "do[] not provide a sound economic basis for assessing the market . . . the way that a proper interchangeability test would."); *Geneva Pharms. Tech.*, 386 F.3d at 496 (refusing to recognize a market of generic warfarin sodium and Coumadin although "the industry undoubtedly acknowledges that Coumadin competes to some extent with generics"); *Lundbeck*, 2010 WL 3810015, at *20 (rejecting FTC's proposed market definition consisting of both NeoProfen and Indocin IV despite internal company documents that refer to a market that consists of NeoProfen and Indocin IV).

b. The products' peculiar characteristics and uses

"The product's peculiar characteristics' refers to the general truth that substitutes in a market often have a strong physical and functional relationship". *Rothery*, 792 F.2d at 218 n.4. A product or group of products constitutes a distinct market when it has "(sufficient) peculiar characteristics and uses which make it distinguishable from all other products". *United States v. Brown Shoe Co.*, 179 F. Supp. 721, 729 (E.D. Mo. 1959), *aff'd*, 370 U.S. 294 (1962)

(quotations omitted). The peculiar characteristics and uses of Galleri and the MCED tests in development place them in different relevant markets.

Unique characteristics. Even aside from the fact it is the only test on the market, Galleri is unique. The test sequences a patient's blood sample to identify the methylation patterns, then takes the data and analyzes it using a machine learning algorithm, which classifies the methylation pattern as a cancer signal or noncancer signal. (PFF ¶ 722.) If a cancer signal is detected, the sample is analyzed again using the machine learning algorithm to predict the cancer's signal of origin. (PFF ¶ 723.) No other test does what Galleri can do. Galleri has been shown to detect more than 50 cancer types with high specificity,[6] and identify the cancer signal of origin with high accuracy. (PFF ¶ 724.) No other test in development has been shown to detect more than 10 cancer types or determine the molecular cancer signal of origin. (PFF ¶¶ 684.1–684.2, 724.)

Most of the tests in development are too underdeveloped to permit a meaningful comparison of their features, and at present are being actively developed as single cancer tests (not MCED tests), but the three for which there are data are readily distinguishable, as illustrated in the below table:

[6] Sensitivity measures how often a test correctly returns a positive result to a patient who has the condition being tested for. (PFF ¶ 172.) Low sensitivity leads to high *false negative* rates. (PFF ¶ 172.) Specificity measures how often a test correctly returns a negative result to a patient who does not have the condition being tested for. (PFF ¶ 173.) Low specificity leads to high *false positive* rates. (PFF ¶ 173.) Sensitivity and specificity are measures of a test's performance in a given study. Because the baseline rate of cancer in the general population is very low, other metrics are needed to predict a screening test's performance when used in clinical settings. One such measure is Positive Predictive Value ("PPV"): the percentage of patients with a positive test who actually have cancer. (PFF ¶ 174.) For example, a specificity of 99.5% translates into about a 40-50% PPV—one of every two individuals with a positive test result would be a false positive. (PFF ¶ 176.1.)

Test	Galleri (GRAIL) 1 Blood Test	CancerSEEK (Exact/Thrive)			PanSeer (Singlera) 1 Blood Test
		1 Blood Test	2 Blood Tests	2 Blood + PET-CT	
Study	CCGA3	DETECT-A			Taizhou L.S.
Types of Cancer	50	10			5
Cancer Signal of Origin	Yes	No	No	Yes	No
Specificity	99.5%	95.3%	98.9%	99.6%	96.1%
Sensitivity	51.5%	30.2%	27.1%	15.6%	94.9%
PPV	44.4%	5.9%	19.4%	28.3%	

(PFF ¶ 725, Table 7.)

In addition to obvious differences in the number of cancers detected, the nature of the testing and the ability to detect cancer signal of origin, there are significant differences between the specificity and sensitivity of the tests. (PFF ¶ 726.) For example, the specificity of Galleri is 99.5% compared to 95.3% for the equivalent version of CancerSEEK. (PFF ¶¶ 725, 726.1.) While those numbers may seem close, the difference between them is huge in the context of a screening test. (PFF ¶ 726.1.) The 4.2% difference means that for every 100,000 patients screened, an additional 4,200 people using CancerSEEK will receive a false positive result that they have cancer. (PFF ¶ 726.2.) The specificity of CancerSEEK comes closer to Galleri only when patients are subjected to two separate blood draws and a full body PET-CT scan. (PFF ¶ 726.3.) The sensitivity of the tests is also not at all comparable, at 51.5% as compared to 30.2%. (PFF ¶ 726.4.)[7] Similarly, Galleri's PPV outperforms CancerSEEK by a significant margin, even when accounting for the follow-up PET-CT. (PFF ¶ 726.5.)

Complaint Counsel, as well as Exact/Thrive witnesses, have argued that GRAIL's claims of being able to detect 50+ cancer types is not comparable to Thrive's finding it can

[7] Further, any analysis of CancerSEEK's characteristics is premature, as Exact is going back to the drawing board with the test and "combining the Exact Sciences and Thrive approaches in one

detect 10 cancer types due because GRAIL only showed this in a retrospective study, whereas Thrive's study was prospective. However, this criticism overlooks the fundamental nature of GRAIL's clinical development program. In CCGA, the case-control trial where Galleri was shown to detect 50+ types of cancer, the "samples were prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples." (PFF ¶ 371.2 (Cote Tr. 3794–95).)

The results of GRAIL's first interventional study, PATHFINDER, bear this assessment out. In PATHFINDER, Galleri has 13 different types of cancer at early stages, including early pancreatic cancer, early liver cancer, early head and neck cancer and a lot of hematologic malignancies. (PFF ¶ 398.3.) As GRAIL's President and Chief Medical Officer Dr. Josh Ofman described, "it was almost like you were standing on the street corner watching healthy 50-year-olds walk by that had no idea they had cancer and seeing the cancers just light up as they walked by. It was really remarkable." (PFF ¶ 398.3.) That Galleri has only detected 13 cancer types in PATHFINDER so far does nothing to cast doubt on its ability to detect 50+ cancer types. To find all 50 cancer types in a real-world population would require hundreds of thousands of people, and PATHFINDER was not designed to do that. (PFF ¶ 398.4.) PATHFINDER was designed to understand the specificity of Galleri and its positive predictive

test." (PFF ¶ 726.6.) [redacted]

value, and on those measures, it confirms Galleri's performance characteristics that were shown in CCGA. (PFF ¶ 398.4.) As Dr. Ofman testified, "it performed pretty close to as we predicted it would, and the PPV that we've seen thus far on the interim seems to be very well-aligned with what we've seen in prior studies. And that's really important because in this field, you know, it's littered with companies that do these small, underpowered studies, case-control studies . . . where they put it into actual clinical care and the tests don't work. And so, you know, there's a lot of skepticism about that, and so it was really important for us to show that the robust CCGA study was able to replicate itself under real-world conditions." (PFF ¶ 398.2.)

Different uses. Because of its unique characteristics, the Galleri test will be used differently than the purported MCED tests in development. The Galleri test is recommended for use in asymptomatic adults aged 50 and older. (PFF ¶ 727.) It is intended to be used in addition to, and not to replace, standard of care screening tests such as mammograms and colonoscopies. (PFF ¶ 727.) It is designed to detect as many cancers as possible as early as possible.

While we do not know exactly what the MCED tests in development will look like, if they were to launch in the future, there is no question that the tests Complaint Counsel cites will be used very differently than Galleri. Most of the tests are single-cancer tests that the developer may use as a starting point for a test that includes an additional cancer or two in the future. (PFF ¶ 728.1.) [redacted]

[redacted]

The overwhelming evidence showed that the purported MCED tests cited by Complaint Counsel are likely to be used very differently from Galleri in the event of launch. (PFF ¶ 729.)

- Guardant. [redacted] As Bill Getty explained, "Galleri is going after something very different, which is just a larger population, test for more things. We are saying use us for colorectal cancer screening ostensibly when we are commercialized." (PFF ¶ 730.1.) [redacted]
- Freenome. [redacted]
- Helio. [redacted] Helio was previously developing a multi-cancer screening test called IvyGene but has since abandoned those efforts. (PFF ¶ 501.1.) [redacted]

[redacted]

- Natera. [redacted]

- FMI. [redacted]

- Exact/Thrive. Exact/Thrive's CancerSEEK requires three separate tests to confirm a positive result: first, a patient takes a baseline blood test, and if that returns a positive result, then the person takes a confirmation blood test. (PFF ¶ 735.) If both the baseline and the confirmatory blood tests are positive, then a patient undergoes a diagnostic full-body PET-CT scan to confirm the results of the blood tests and to localize the potential cancer. (PFF ¶ 735.) [redacted]

[8] A test developer focusing on a single cancer screening test or a test directed to only a handful of targeted cancer types may elect to focus on the test's sensitivity, so it can serve as a "rule-out" test that does not require follow-up to confirm a negative result. As a corollary, in such tests, a lower level of specificity (and increase in the false-positive rate) can be tolerated, especially where there is a standard of care screening available, such as a colonoscopy, that a doctor can reflex to following a positive result. (PFF ¶ 733.3.)

[redacted]

- Singlera. Singlera's PanSeer assay has been shown to detect five types of cancer at 96.1% specificity in a retrospective, observational study of 418 participants. (PFF ¶ 736.) On that measure alone, it is likely that Singlera would not be used in the same target population as Galleri. (PFF ¶ 736.) This is further confirmed by the fact that any patient testing positive on PanSeer would then undergo an additional blood test and/or follow-up imaging to allow tissue of origin mapping. (PFF ¶ 737.)

Complaint Counsel appears to contend that Exact/Thrive's CancerSEEK is the nearest competitor to Galleri. (PFF ¶ 738.) But the patient experience with the only version of the CancerSEEK test for which Exact/Thrive has published any data is very different from that same patient's experience with Galleri [redacted]. The version of CancerSEEK used in DETECT-A, Exact/Thrive's most recent published study, consisted of three separate tests—two blood draws and a PET-CT scan, each collected at a different time (PFF ¶ 739)—makes it very different from Galleri, which consists of one blood draw that may be conducted as part of an annual physical exam. (PFF ¶ 739.) Moreover, a comparison between Galleri and the first blood draw in CancerSEEK further shows the significant differences between them. As shown in the table below, the performance of Galleri is superior to CancerSEEK's single blood draw:

Table 8

Test	Galleri	CancerSEEK 1 Blood Test
Study	CCGA3	DETECT-A
Types of Cancer	50	10
Cancer Signal of Origin	Yes	No
Specificity	99.5%	95.3%
Sensitivity	51.5%	30.2%
PPV	44.4%	5.9%

(PFF ¶ 740, Table 8.)

[redacted] Complaint Counsel has certainly not identified evidence of likely substitution in the face of these significant differences between the tests to support its claim that they will compete in the same relevant antitrust market.

Products have been placed in separate antitrust markets based on differences in characteristics and uses that are less pronounced than the differences between the characteristics and uses of Galleri and other MCED tests in development. *See, e.g.*, *RAG-Stiftung*, 436 F. Supp. 3d at 302 n.15 (separating hydrogen peroxide into distinct markets based on their end uses because "end uses within standard grade, by their definition, have 'peculiar characteristics and uses'"); *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 23 (D.D.C. 2017) (placing Medicare Advantage and Original Medicare into distinct markets due to distinct characteristics of Medicare Advantage, such as limited out-of-pocket expenses and supplemental benefits).

c. Unique production facilities.

Differences in production facilities further undermine Complaint Counsel's claim that Galleri belongs in the same market as any and every putative MCED test in development.

"The cross-elasticity of production facilities may also be an important factor in defining a product market." *Brown Shoe*, 370 U.S. at 325 n.42. "If a product requires unique production facilities, and the producer raises the price above the competitive level, the ability of other producers to shift resources to make the product would be limited, and the market definition should be likewise limited." *Rothery*, 792 F.2d at 218 n.4; *see also IGT v. All. Gaming Corp.*, 702 F.3d 1338, 1347 (Fed. Cir. 2012) ("[T]here are no unique production facilities or

specialized vendors for wheel games versus ordinary gaming machines; one can just as easily produce a gaming machine with a square bonus as one with a circular bonus."). Courts are more likely to find that two products are in separate antitrust markets under this factor if they have a need for specialized technology. *See Epic Games*, 2021 WL 4128925, at *42 (excluding non-game apps from the market of game apps as "game developers often use specialized technology to create their apps" and "tend to specialize in the development of game apps and related gaming software").

[redacted]

As part of the CCGA study, GRAIL determined that the most appropriate biomarkers to identify early cancer through blood tests were methylation sites, in which plasma cfDNA is subjected to bisulfite conversion, prepared as a dual indexed sequencing library and enriched using standard hybridization capture conditions, followed by paired-end sequencing. (PFF ¶ 741.3.) GRAIL developed a proprietary method for library preparation to efficiently prepare methylated DNA fragments for sequencing, and then developed proprietary machine learning algorithms to take those methylation signals and make a prediction about whether or not a patient has cancer, and if they do, what type of cancer. (PFF ¶ 741.4.) This approach is unique to GRAIL, and is even distinct from that of others who seek to include methylation

biomarkers in their own test. [redacted]

The library preparation and back-end algorithms used by the other putative MCED test developers are different from GRAIL's. (PFF ¶ 742.) Exact/Thrive is focusing only on 16 gene mutations and nine protein sites to screen for ten cancer types. (PFF ¶ 742.1.) [redacted] Freenome's approach combines data from whole-genome sequencing, DNA methylation, and protein quantification using a multiomics approach, [redacted]

GRAIL's use of "specialized technology" distinct from the other putative MCED test developers demonstrates that Galleri and these putative tests in development do not belong in the same market. *See Epic Games*, 2021 WL 4128925, at *42. In any event, Complaint Counsel has not shown there to be cross-elasticity of production facilities between Galleri and the putative MCED tests in development to merit including them in the same market. *See Brown Shoe*, 370 U.S. at 325 n.42; *Rothery*, 792 F.2d at 218 n.4.

d. Distinct customers.

Complaint Counsel has failed to show that the putative MCED tests in development would have the same group of customers as Galleri, underscoring that Galleri is not in the same market as these putative tests.

A finding that a product has distinct customers "may indicate unique product attributes, which refers again to the fact that products with distinct physical and functional attributes tend to be priced differently." *Rothery*, 792 F.2d at 218 n.4. A "high degree of differentiation" between one product and another "means that for many customers, only [the

highly differentiated product] will do." *United States v. Grinnell Corp.*, 384 U.S. 563, 574 (1966). Products that are "uniquely attractive" to customers can "constitute[] a separate market for which there is no reasonable substitute." *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 112 & n.49 (1984).

Because the MCED tests in development that Complaint Counsel seeks to include in the market are in early stages of development, it is impossible to say for certain by which customers they might be used. But what is clear already (and Complaint Counsel has not demonstrated otherwise) is that these tests are seeking different indications, and therefore (if they ever launch) they will have distinct customers, from Galleri. Again, Galleri can detect the presence of more than 50 cancers as well as the cancer signal of origin (PFF ¶ 744.) GRAIL expects Galleri will be ordered annually as part of a patient's annual physical exam. (PFF ¶ 744.) The test is likely to be of interest to anyone above the age of 50 who wishes to know whether they have cancer, regardless of location in the body, at an early stage, through a single blood draw, without any need for a PET-CT scan and the risks such a scan entails. (PFF ¶ 744.)

In contrast, an MCED test capable of detecting only two or three cancer types would be used only by customers with reason to suspect susceptibility to the few cancers the test could detect, [redacted] The "high degree of

differentiation" between Galleri and the putative MCED tests in development "means that for many customers, only [Galleri] will do." *Grinnell Corp.*, 384 U.S. at 57.

e. Distinct prices.

Products with distinct prices "suggest[] that cross-elasticity of demand is low", *Rothery*, 792 F.2d at 218 n.4, and should be placed in different antitrust markets. The "distinct prices" inquiry is quantitative, as it goes directly to the economic criteria that make one market distinct from another." *Rothery*, 792 F.2d at 218 n.4; *see also In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 985–86 (C.D. Cal. 2012) (noting that "distinct prices . . . lend themselves well to a quantitative approach").

A quantitative inquiry here starts and ends with Galleri. At present, Galleri is the only MCED test with a price, currently selling for $949 [redacted]

Complaint Counsel failed to show that any of the putative MCED tests will have a similar price to Galleri. In fact, it is virtually impossible to compare the price of Galleri to tests not yet in existence.[9] None has a published price and most have not determined what their prices might be. (PFF ¶ 750.) Singlera, for example, has said that it "couldn't know right now" at what price Singlera plans to market PanSeer. (PFF ¶ 750.1.) [redacted] There is no evidence to suggest Helio, [redacted] has made any determination on the price of any putative test that detects multiple cancer types. (PFF ¶ 750.4.)

[9] (PFF ¶ 748 ("In the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price.").)

In addition, it is undisputed that an MCED test's price will in large part depend on the level of payor adoption, and that payor adoption will depend on the development of extensive evidence to establish clinical utility of a MCED test. (PFF ¶ 756.) [redacted]

Accordingly, Complaint Counsel has failed to meet its burden to establish that other MCED tests share (or likely will share if and when launched) a distinct price with Galleri. [redacted]

f. Sensitivity to price changes

"If a slight decrease in the price of product A causes a considerable number of customers of product B to switch to A, that would indicate that a cross-elasticity of demand exists between A and B and that they compete in the same product market." *Arch Coal*, 329 F. Supp. 2d at 120. Therefore, courts should "exclude any other product to which, within

reasonable variations in price, only a limited number of buyers will turn." *Id.* (quoting *Times–Picayune Publ'g Co. v. United States,* 345 U.S. 594, 612 n. 31 (1953)).

Just as Complaint Counsel has not demonstrated that the price of Galleri will share a similar price with purported MCED tests still in development that will likely have very different features and indications than Galleri, Complaint Counsel also is unable to say, and has not demonstrated, whether the price of Galleri will be sensitive to the availability and pricing of the tests in development that Complaint Counsel argues should be in the same market as Galleri. (PFF ¶ 752 ("Q. Based on what you know about healthcare markets and your determinations about competition between LUNAR-2 and Galleri, once LUNAR-2 is on the market at a given price, if that price were to increase by, let's say, $10, you could not say one way or another that that increase would cause doctors to prefer Galleri over LUNAR-2; right? A. No. Q. In other words, what I've just asked you is correct; you agree with my statement. A. Yes, I do.").)

[redacted] On top of that, there is no record evidence that an increase in price to the 50-cancer test is likely to cause consumers to switch to a two- or three-cancer test. (PFF ¶ 754.)

In any case, despite having the burden to prove the relevant market, Complaint Counsel did not undertake any study concerning the price sensitivity of Galleri vis-à-vis any of

the purported MCED tests in development. (PFF ¶ 755.) Complaint Counsel did not offer any evidence that the prices of Galleri will be sensitive to changes in the prices of the MCED tests in development. (PFF ¶ 755.1.)

Where, as here, a plaintiff cannot show price sensitivity between products in the proposed market based on an appropriate economic analysis, courts regularly find that a plaintiff cannot meet its burden to prove a relevant market, even in instances where the plaintiff has presented more than Complaint Counsel here—for example, survey evidence. *See, e.g., Se. Mo. Hosp.*, 642 F.3d at 616 (finding that the plaintiff failed to prove a relevant market because the expert asserted that customers were not sensitive to price changes but offered "no market studies to support this claim, making the assertion without analytic or even anecdotal evidence"); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 664 (7th Cir. 2004) (finding that the plaintiff failed to prove that at-shelf dispensers were a relevant market because he "introduced no econometric evidence of any kind" and instead "offered a potpourri of survey research and armchair economics"); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc*., 7 F.3d 986, 997 (11th Cir. 1993) (rejecting the plaintiff's proposed market for providing "no basis other than guesswork" for concluding that consumers would be sensitive to price changes); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993) (rejecting market definition where expert's opinion based on "limited anecdotal evidence" and "[t]here was no detailed examination of market data or any analysis of cost, comparable usage, or comparative features of other competing products").

g. Specialized vendors

Finally, specialized vendors "may indicate unique product attributes, which refers again to the fact that products with distinct physical and functional attributes tend to be priced differently." *Rothery*, 792 F.2d at 218 n.4. A product has specialized vendors when it has

"avenues for distribution . . . which differ[] in both kind and degree". *Epic Games*, 2021 WL 4128925, at *42.

While all purported MCED tests except for Galleri are still in early stages of development, all available evidence indicates that Galleri and the purported MCED tests in development have unique attributes which involve specialized vendors. Different vendors provide different medical services to patients. For example, a blood test may be performed in a physician's office by a phlebotomist, while imaging or other scanning must be performed in a specialist's office or through other means. (PFF ¶ 758.) Because the Galleri test is exclusively a blood test, it can be performed in a single physician's office alone. (PFF ¶ 759.) By contrast, the version of Thrive's CancerSEEK assay that is the subject of clinical studies entails at least three separate tests with two different vendors: a blood draw and the use of a PET-CT scan to confirm positive results and determine cancer signal of origin. (PFF ¶ 760.) Similarly, based on the current published data, a patient with a positive result from Singlera's PanSeer test could potentially undergo follow-up imaging to allow tissue of origin mapping. (PFF ¶ 761.)

[redacted]

Should additional imaging be required to obtain cancer signal of origin—which all three entities concede will be required—those putative MCED tests would likely require specialized vendors that are not utilized in the routine workflow of the Galleri test, to provide a result to the patient. (PFF ¶ 763.)

Products are routinely held to fall in different markets where they are sold by specialized vendors or distributed differently. *Epic Games, Inc. v. Apple Inc*., No. 4:20-CV-

05640-YGR, 2021 WL 4128925, at *42 (N.D. Cal. Sept. 10, 2021) (separating game apps from the non-game apps market because "game apps have multiple avenues for distribution," which "differ[] in both kind and degree from those available to non-gaming apps" and are "specifically designed for such games—and not non-gaming apps").

* * *

In arguing that the "*Brown Shoe* practical indicia show MCED tests constitute a relevant product market" (CC Pretrial Br. at 32), Complaint Counsel selectively employed the *Brown Shoe* factors to differentiate "MCED Tests" from minimum residual disease ("MRD"), diagnostic aid to cancer ("DAC"), therapy section and single-cancer screening tests. However, that argument overlooks and fails to address the key question in this case on market definition. The relevant question is not whether MCED tests are part of a relevant antitrust product market that also includes MRD, DAC, therapy selection and single-cancer screening tests, but whether the MCED tests identified by Complaint Counsel are in the same relevant product market as Galleri. Thus, Complaint Counsel's arguments are strawmen. Notably, Complaint Counsel's pretrial brief makes essentially no effort to apply the *Brown Shoe* factors to analyze whether Galleri is in the same market as the MCED tests in development that Complaint Counsel lumps with Galleri. It is not.

As just shown, the *Brown Shoe* factors point decidedly against Complaint Counsel's' alleged market. *See, e.g.*, *RAG-Stiftung*, 436 F. Supp. 3d at 302 n.15 (rejecting the FTC's proposed market of standard grade hydrogen peroxide because the Brown Shoe factors pointed to a narrower market based on the "peculiar characteristics and uses" of hydrogen, the customers that "tend to be different" but still overlap, and the distinct prices); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (rejecting the plaintiff's proposed

market because of insufficient evidence of price sensitivity and countervailing evidence of a different market due to its distinct customers).

4. The Alleged Market Fails the Hypothetical Monopolist Test.

In addition to the *Brown Shoe* practical indicia, courts (and the Commission) rely on the approach set forth in the Merger Guidelines to define the relevant product market—the hypothetical monopolist test. *See, e.g., Staples*, 190 F. Supp. 3d at 121–22; *Sysco*, 113 F. Supp. 3d at 33-34; *ProMedica*, 2012 FTC LEXIS 293, at *40-41 (citations omitted); *Polypore*, 2010 WL 9549988 at *11, *15. That test asks whether a hypothetical monopolist of a particular group of substitute products could profitably impose a SSNIP, typically five percent, on at least one of the products in the candidate market, including at least one product sold by one of the merging firms. Horizontal Merger Guidelines §§ 4.1.1-4.1.3 (2010). "If enough consumers are able to substitute away from the hypothetical monopolist's product to another product and thereby make a price increase unprofitable, then the relevant market cannot include only the monopolist's product and must also include the substitute goods. On the other hand, if the hypothetical monopolist could profitably raise prices by a small amount, even with the loss of some customers, then economists consider the monopolist's product to constitute the relevant market." *Sysco*, 113 F. Supp. 3d at 33. The hypothetical monopolist test is typically based on prices that would "likely prevail absent the merger" or, if prices are likely to change absent the merger, the test may use "anticipated future prices". Horizontal Merger Guidelines § 4.1.2 (2010)..

To show the hypothetical monopolist test is met here, Complaint Counsel relies exclusively on the testimony of Dr. Fiona Scott Morton. (PFF ¶ 764.) [redacted]

[redacted] *See In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 985; *see also Se. Mo. Hosp.*, 642 F.3d at 616 (rejecting plaintiff's expert's conclusion that a SSNIP in the relevant market would not cause customers to switch when there were "no market studies to support [the] claim" and the "assertion [was] without analytic or even anecdotal evidence."); *Vollrath*, 9 F.3d at 1462 (rejecting market definition where plaintiff's expert's opinion was based on "limited anecdotal evidence" and "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or

comparative features of other competing products."); *Reifert*, 450 F.3d at 318 (requiring that "a plaintiff prove that products are good substitutes *using economic evidence*; a conclusory assumption of competition where products or services appear to be similar is insufficient") (emphasis added).

In addition, Dr. Scott Morton did not attempt to fill the information gaps in her assessment using surveys or other means, including information about the preferences and likely switching behavior of clinicians, patients and payors related to the products she includes and excludes from her proposed MCED market. (PFF ¶ 767.) She did not attempt to analyze substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. (PFF ¶ 767.) For instance, the need to obtain payor coverage of NGS-based screening tests will exert pressure on test developers to keep prices low when they commercialize their products. [redacted]; PFF ¶ 767.1 (Katz, Trial Dep. at 19-20) ("[T]here's an information gap there then because we don't have the actual experience and she didn't . . . attempt to fill those information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior.").)

Dr. Scott Morton's failure to account for payor adoption in this way is compounded by her failure to assess how the possible characteristics of the MCED tests in development might impact the likelihood of switching within her defined market. (PFF ¶ 768.)

[redacted] However, her entire analysis consists of a thought exercise in which she weighed the evidence shown to her by her staff and Complaint Counsel and pronounced that the hypothetical monopolist test is satisfied. [redacted]

[redacted] That is not permissible expert testimony. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("Expert testimony is useful as a guide to interpreting market facts, but it is not a substitute for them."); *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1435–36 (9th Cir. 1995) ("In the context of antitrust law, if there are undisputed facts about the structure of the market that render the inference economically unreasonable, the expert opinion is insufficient to support [a finding of fact].").

In any case, courts will typically reject an expert's "proposed product market definition [based] entirely upon his *qualitative* assessment of the market, without any supporting *quantitative* economic analysis." *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 985; *see also Se. Mo. Hosp.*, 642 F.3d at 616 (rejecting expert conclusion that a SSNIP in the relevant market would not cause customers to switch when there were "no market studies to support [the] claim" and the "assertion [was] without analytic or even anecdotal evidence"); *Reifert*, 450 F.3d at 320 ("While the 'practical indicia' named in *Brown Shoe* . . . are important considerations in defining a market, they were never intended to exclude economic analysis altogether"); *ABS Glob., Inc. v. Inguran, LLC*, No. 14-cv-503-wmc, 2016 WL 3963246, at *14 (W.D. Wis. July 21, 2016) ("[This] Circuit has repeatedly emphasized the need for both a quantitative and qualitative economic analysis in arriving at a market definition[.]"); *Vollrath*, 9 F.3d at 1462 (rejecting market definition where "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or comparative features of other competing products"); *Oracle Corp.*, 331 F. Supp. 2d at 1145–49 (expert included significant, specific and extensive analysis of the factors thought to be relevant to making a hypothetical claim based on a SSNIP). Imagining a scenario in which the SSNIP test might be satisfied is not the same thing as proving it, especially where,

as here, Dr. Scott Morton did not attempt to fill the information gaps using surveys or other means, did not attempt to analyze substitution from the perspective of payors and did not attempt to use the available information about the characteristics of the tests to assess whether switching is likely within her defined market. (PFF ¶ 767.) Using "qualitative evidence" is no different than doing a market definition analysis using the *Brown Shoe* factors—which Dr. Scott Morton does not reliably analyze, and which the alleged market does not satisfy for the reasons discussed above.

[redacted] Her opinion does not "incorporate all aspects of the economic reality" of the relevant market, amounts to "mere speculation" and therefore should not be admitted. *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000).

* * *

Defining a relevant product market generally requires a detailed examination of "market data, figures or other relevant material adequately describing the nature, cost, usage or other features of competing products." *Grason Electric Co. v. Sacramento Mun. Util. Dist.*, 571 F. Supp. 1504, 1521 (E.D. Cal. 1983) (quoting *Morton Bldgs. of Neb. Inc. v. Morton Bldgs., Inc.*, 531 F.2d 910, 919 (8th Cir. 1976). "Expert testimony that is speculative is not competent proof and contributes nothing to a legally sufficient evidentiary basis." *Concord Boat*, 207 F.3d at 1057. (internal quotations omitted). Thus, Dr. Scott Morton's market definition opinions should be disregarded.

5. Complaint Counsel's Proposed Relevant Market Depends on Subjective and Changing Policy Assessments, Rather Than Established Law and Objective Evidence.

Complaint Counsel seeks to dismiss the shortcomings in its proof by asserting that the relevant market is nascent and that there is limited evidence available to it. (PFF ¶ 771.) It suggests that the law is specially written to protect nascent markets and that such markets are not inoculated from application of the antitrust laws. (PFF ¶ 771.)

While it is true that Galleri is a nascent product, that other MCED tests in development do not even yet exist and that there is limited economic evidence, none of this relieves Complaint Counsel of its burden to prove the relevant market. The law does not set a different standard for establishing a nascent market. *See, e.g., Apartment Source*, 1999 WL 349938, at *1 (rejecting the plaintiffs' proposed market because "[a]n emerging submarket that has not yet developed into a distinct and identifiable market by definition is not well-defined, and therefore does not constitute a relevant product market under Section 2 of the Sherman Act."); *Epic Games*, 2021 WL 4128925, at *56 , 2021 WL 4128925, at *56 (N.D. Cal. Sept. 10, 2021) (requiring all products in the mobile game apps market to be reasonably interchangeable and thus excluding certain gaming services from the product for being "too new" for the court to determine "whether consumes [*sic*] will or do consider these products reasonably interchangeable").

Complaint Counsel's lax approach would effectively relieve it of the burden of proof and substitute the FTC's subjective and changing policy assessments for established law and objective evidence. No case supports Complaint Counsel's approach to market definition, which relies on platitudes about innovation instead of analysis grounded in law and fact (CC Pretrial Br. at 2, 5 (noting that "Grail and its [alleged] competitors are engaged in an innovation

race")).[10] "Innovation is intangible, uncertain, unmeasurable, and often even unobservable, except in retrospect." Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 Antitrust L.J. 19, 27 (1995). Relying on truisms about innovation instead of rigorous analysis greatly increases the likelihood of false positives under Complaint Counsel's proposed approach—a finding that a merger will substantially lessen competition in a relevant innovation market when, in fact, it would not. *See* Federal Trade Commission Hearings on Global and Innovation-Based Competition 917 (Oct. 25, 1995) (testimony of Richard T. Rapp) (testifying that "[t]he risk of false positives is high because we can't measure innovative output or innovative output the way that we measure output in product markets"). The potential harm from these false positives is especially great where, as here, there is unrefuted evidence that the Transaction will save lives. (*See* PFF ¶¶ 1117–1117.3.)

Complaint Counsel's reliance on innovation principles to compensate for the infirmity of its case relies on a theory of harm that is not based on the ability of the merged entity to exercise market power but rather on the effects of the merger on abstract notions of competition. This approach is flawed, because, as a former Director of the Antitrust Division's Economic Policy Office explained: "the research and development that is described as being of concern is not happening in a market . . . There are no arm's length transactions between suppliers and customers. There are no prices, there are no readily recognized indicia of market

[10] *See OrthoAccel Techs., Inc. v. Propel Orthodontics, LLC*, No. 4:16-CV-00350-ALM, 2017 WL 1213629, at *3 (E.D. Tex. Apr. 3, 2017) (requiring plaintiff to "plead a relevant product market in precise economic terms" despite it being "difficult to assess cross-elasticity of demand for nascent products in a relatively new market"); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.*, No. C-09-3854 MMC, 2010 WL 1541257, at *3 (N.D. Cal. Apr. 16, 2010), *aff'd*, 433 F. App'x 598 (9th Cir. 2011) (rejecting the plaintiffs' alleged product market because they failed to sufficiently allege interchangeability "both in the pharmaceutical product markets and in the innovation market for pharmaceutical products").

power." Federal Trade Commission Hearings on Global and Innovation-Based Competition (1995) (testimony of Lawrence White). Even if an innovation market approach were acceptable, Complaint Counsel cannot rely on it here because Dr. Scott Morton did not perform the necessary analysis. For an innovation market, the relevant definitional questions are: (i) "[D]id a hypothetical monopolist that controlled some set of assets to innovation . . . find it profitable to cut back on innovation?"; and (ii) to find the boundaries of the market, what are the firm's "capabilities to do innovation?" (PFF ¶ 772.) Dr. Scott Morton did no such analysis. (PFF ¶ 772 (RX6004 (Katz Trial Dep. at 26) ("I think it's clear that Professor Scott Morton when she applies her hypothetical monopolist test is applying it to defining a product market, not an innovation market.").) And Complaint Counsel offered no other evidence demonstrating that the answer to these critical questions support its allegations. Plainly, Complaint Counsel has not met its burden to prove an innovation market comprising Galleri and other putative MCED tests in development.

B. Complaint Counsel Also Failed To Prove Its Alleged Related Product Market.

Complaint Counsel contends that it is not required to prove a related product market but asserts that "[h]ere, Illumina's NGS instruments and consumables are related products to MCED tests, serving as critical inputs necessary to their development and commercialization." (CC Pretrial Br. at 49.) Especially given its theory of the case, Complaint Counsel was required to prove a related product market to prevail, and it came nowhere close to doing so. Thus, in addition to the fact that it failed to prove a relevant market, Complaint Counsel's challenge to the Transaction runs aground because it was unable to prove a related product market.

1. Complaint Counsel Was Required To Prove a Related Product Market.

Complaint Counsel alleges that the Transaction will harm competition because it will empower and incent Illumina to raise costs to GRAIL's rivals who will have no alternative to Illumina's NGS instruments and consumables. (CC Pretrial Br. at 61–62.) It is undisputed that Complaint Counsel bears the burden to prove its case, including the definition of the relevant market(s). *AT&T I*, 310 F. Supp. 3d at 194. Because proof of a related product market is an element of Complaint Counsel's case, it bears the burden to prove a related product market. *Arch Coal*, 329 F. Supp. 2d at 116 ("[P]laintiffs have the burden on every element of their Section 7 challenge, and a failure of proof in any respect will mean the transaction should not be enjoined.").

Complaint Counsel has argued that it is not required to prove a related product market, but that is incorrect. In challenging a vertical merger, Complaint Counsel must demonstrate that "by altering the terms on which it provides a related product to one or more of its rivals, [the merged firm] would likely be able to cause those rivals to lose significant sales in the relevant market or otherwise compete less aggressively for customers." Federal Trade Commission, *Commentary on Vertical Merger Enforcement* (Dec. 2020) (withdrawn Sept. 2021) at 9. Defining a cognizable related product market is a necessary element of making this showing, since "[v]ertical restraints often pose no risk to competition unless the entity imposing them has market power, which cannot be evaluated unless the Court first defines the relevant market." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285, n.7 (2018); *see also Auburn News Co. v. Providence J. Co*., 659 F.2d 273, 278 (1st Cir. 1981) ("Where substantial market power is absent at any one product or distribution level, vertical integration will not have an anticompetitive effect."); *Fruehauf.*, 603 F.2d at 353.

The requirement to prove a related product market can also be inferred from prior decisions on vertical mergers, even though courts may not have expressly considered the question. *Fruehauf Corp.* concerned a government challenge of the merger between Fruehauf, the nation's largest manufacturer of truck trailers, and Kelsey, a manufacturer of various components to truck trailers, including heavy duty wheels ("HDWs") and antiskid braking devices ("ASBDs"). 603 F.2d at 347. The FTC alleged that the acquisition would harm competition in the truck trailer market by enabling Kelsey to divert to Fruehauf HDWs that would otherwise go to Fruehauf's competitors. *Id.* at 354. The court rejected this contention as "having "no appreciable evidentiary support." *Id.* Critically, the *Fruehauf* court held that in assessing the anticompetitive effect of a vertical merger, it must measure "the degree of market power that would be possessed by the merged enterprise and *the number and strength of competing suppliers and purchasers*". *Id.* at 353 (emphasis added). Defining the relevant markets at all levels of the distribution chain is necessary to conduct such an analysis and the *Fruehauf* court did so: it defined the truck trailer market, the HDW market and the ASBD market, with reference to total sales volume and Fruehauf's and Kelsey's respective market shares in each one. *Id.* at 349–51. Complaint Counsel has failed to undertake such an analysis here.

Further, commentary on the Vertical Merger Guidelines supports the necessity of defining a related product market, especially in cases of alleged input foreclosure such as this one. In such cases, "it will be necessary to understand what inputs are included in the 'related product' category when there is actual input substitution." Jonathan B. Baker, Nancy L. Rose, Steven C. Salop & Fiona Scott Morton, *Recommendations and Comments on the Draft Vertical Merger Guidelines* (Feb. 24, 2020) at 6-7. In addition, it is necessary to understand (i) "whether

price increases by the merging firm that produces the 'related product' will lead to accommodating price increases by its competitors that could exacerbate the anticompetitive potential of a price increase by the upstream merging firm" and (ii) "measure the share of output accounted for by the related product." *Id.* at 6–7

In its pre-trial brief, Complaint Counsel cited both *Brown Shoe* and *du Pont* to support its theory that it does not bear the burden to show a related product market. (CC Pretrial Br. at 49 (citing *Brown Shoe*, 370 U.S. at 325; *E.I. du Pont de Nemours & Co.*, 353 U.S. at 593–95.) The burden to prove a related product market was not at issue in either case, and therefore cannot be fairly read to support Complaint Counsel's desired conclusion. In *Brown Shoe*, the Supreme Court held that the "relevant line[s] of commerce" were the markets for men's, women's and children's shoes, rather than the narrower proposed markets that Brown Shoe suggested. 370 U.S. at 326 (noting that Brown argued the district court's market definitions "fail to recognize sufficiently 'price/quality' and 'age/sex' distinctions in shoes"). While the Court did not consider the issue of a plaintiff's burden to define both a related and relevant product market, it explicitly discussed both Brown Shoe's and Kinney's market power in the *manufacture* and *retail* of men's, women's and children's shoes, respectively, as it related to the vertical harm that would arise from the merger. Brown was the fourth largest manufacturer and Kinney owned the largest chain of retail stores in the country. *Id.* at 332–33. Because of Kinney's market power in the related market, Brown would use its ownership of Kinney to force Brown shoes into Kinney stores, thereby foreclosing Brown's manufacturer competitors from access to Kinney's retail channel. *Id.* at 331–32. Kinney's market power in the related retail stores market was critical to such a finding.

Complaint Counsel also cites to the (now withdrawn) Vertical Merger Guidelines to support its claim that it need not define a related product market. However, nowhere did the Guidelines suggest that defining a related product market is unnecessary. In order to assess "the merged firm's rivals' ability to switch to alternatives to the related product", the Guidelines suggested reviewing "the types of evidence the Agencies use to evaluate customer switching when implementing the hypothetical monopolist test." Vertical Merger Guidelines § 4.a (2020) (withdrawn 2021). Invoking a hallmark principle of market definition to assess alternatives to the related product is inconsistent with a claim that the Guidelines did not require defining a related product market.

2. Complaint Counsel Provided No Credible Evidence to Prove its Alleged Related Product Market.

Complaint Counsel defines the related product market as "Illumina's NGS instruments and consumables". (PFF ¶ 773.) The narrowness of this alleged market, in which Illumina would obviously be a monopolist (as it would necessarily be the only supplier), stands in stark contrast to the very broad manner in which Complaint Counsel seeks to define the relevant product market (as discussed in Section I.A. above).

Tellingly, Complaint Counsel does not even attempt to define a related market in which Illumina is a monopolist. In discussing the relevant product market, Complaint Counsel acknowledges that an appropriate antitrust market is dependent on reasonable interchangeability, the *Brown Shoe* practical indicia and the hypothetical monopolist test. (PFF ¶ 774.) Neither Complaint Counsel nor its expert (Dr. Scott Morton) did the requisite analysis of the related product market, despite the availability of quantitative data. (PFF ¶ 775.) [redacted] That is not analysis; it is *ipse dixit*.

In concluding that Illumina's NGS instruments and consumables comprise the related product market, Complaint Counsel did not conduct any detailed examination of "market data, figures or other relevant material adequately describing the nature, cost, usage or other features of competing products." *Grason Electric*, 571 F. Supp. at 1521 (citation omitted). Complaint Counsel did not undertake any effort to conduct a SSNIP test to determine whether the boundaries of the related product market were limited to Illumina's NGS systems, other NGS systems, or non-NGS systems. *See Sysco*, 113 F. Supp. 3d at 33. Rather, it simply asserted that the related product market consisted of Illumina's NGS instruments and consumables, and nothing else.

3. There Are Currently Other Viable NGS Platforms for Cancer Screening

Contrary to Complaint Counsel's unproven contention, there are other viable NGS platforms on the market that can support MCED tests in development. BGI already has a commercially available NGS platform, markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. (PFF ¶ 777.) BGI is currently enjoined from launching its sequencing instruments and related reagents in the United States due to its infringement of a certain Illumina patents that expire in 2022 and 2023. (PFF ¶ 777.1.) BGI may enter the U.S. market by August 2022. (PFF ¶ 777.2; *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the patents-in-suit—as they are permitted—they must include the following conspicuous written disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'").) [redacted]

BGI's DNBSEQ sequencer's reported accuracy is comparable to Illumina's sequencers, and guarantees more than 80% of bases with quality score greater than Q30 (over 99.9% accurate). (PFF ¶ 777.4.) [redacted]

In addition to BGI and Thermo Fisher, Oxford Nanopore ("ONT") is also a viable alternative for MCED developers. (PFF ¶ 779.) Recent improvements by ONT in the past year have included adaptations to its sequencers and library preparation that makes this platform more suitable for use for multi-cancer screening. (PFF ¶ 779.1.) ONT's instruments reportedly will compete with Illumina's on throughput, accuracy and cost. (PFF ¶ 779.2.) ONT's highest throughput instrument, the PromethION, is claimed to have a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the

S4 flow cell. (PFF ¶ 779.2.) ONT claims its instruments have similar accuracy to Illumina. (PFF ¶ 779.3.) And, as shown in the table below, ONT claims to offer per Gb sequencing costs that are lower than what Illumina offers.

The evidence demonstrates that liquid biopsy test makers view these platforms as viable substitutes for Illumina's platform. (PFF ¶ 780.) [redacted] Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment. (PFF ¶ 780.4.) [redacted]

[redacted]

4. There Are Many New NGS Sequencers in Development and Likely Entrants to the NGS Market

In addition to the viable platforms already on the market, there are also many NGS platforms in development and likely to enter the market in the near future that will be viable platforms for MCED tests. (PFF ¶ 782.) Illumina fully anticipates a flood of upstream competition in the near future, as is reflected in Illumina's ordinary course strategy documents.

[redacted]

- Singular Genomics. Singular Genomics has developed an NGS platform, the G4 System, which launched at the end of 2021, and expects to begin shipping units in the second quarter of 2022. (PFF ¶ 783.) The G4 System's reported performance characteristics are comparable to those of Illumina's NextSeq and NovaSeq systems, with read lengths of 50 to 150 bases, 400 Gbs per sequencing run, high speed sequencing at 4-minute cycle times, and high accuracy of 99.7% on 150 base reads. (PFF ¶ 783.1.) [redacted]

- Ultima Genomics. [redacted]
- Roche. [redacted]
- Element. [redacted]

- Omniome. Omniome, recently acquired by PacBio, is developing an NGS sequencer using its sequencing-by-binding technology. (PFF ¶ 787.) [redacted] The combined PacBio and Omniome have said they would specifically target the cancer screening market and believe Omniome's reportedly better data accuracy will help them achieve that. (PFF ¶¶ 640–640.1.)

[redacted]

In dismissing the evidence of these emerging NGS platforms (not to mention those already on the market) as speculative, Complaint Counsel ignores that its own alleged relevant market is predicated on far more speculative entry by purported MCED test developers. Complaint Counsel cannot have it both ways. It cannot base its alleged market definition on speculation about future entry by MCED tests that are, at best, in early stage development (*see* Section I.A *supra*), while simultaneously discarding evidence of actual competition and future entry by NGS developers in defining the alleged related product market. Complaint Counsel

does not offer—and Respondents are not aware of—any principled basis for the Court to adopt such an asymmetrical approach to the evidence concerning market definition. (PFF ¶ 789 ("[A]ll I can do is point out the asymmetry in [Complaint Counsel's] analysis . . . in which [it] assumes that the MCED products are going to come into existence, but the NGS alternatives to Illumina are not.").)

5. Customers Can Adapt Assays Developed on Illumina's Platforms to Another Platform

[redacted] However, that argument ignores the evidence adduced in Complaint Counsel's own case. As that evidence shows, even absent the Transaction, it is likely that a test developer will need to switch between different sequencing platforms (such as between different Illumina NGS platforms) during the course of developing a screening test. (PFF ¶ 791.) Test developers routinely re-validate their tests to account for new and improved technology relating to consumables or sequencers, new developments in their tests, or for any number of other reasons. (PFF ¶ 791.1.) These revalidations are integral to a sound business plan for any test developer. (PFF ¶ 791.1.) [redacted]

Other screening test developers have, in fact, switched platforms for their MCED tests in development. (PFF ¶ 793.) [redacted] Given the increased availability of competing NGS platforms in the next few years, screening test developers have many opportunities to switch from Illumina's platform to another platform, with a process no more burdensome than that they would use to switch to the next generation of Illumina sequencers. (PFF ¶ 794.) In addition, it is in the interest of other sequencing companies to make switching as seamless as [redacted]

[redacted]

* * *

Complaint Counsel's failure to properly define a related product market is fatal to its case, as proof of a related product market is an element of Complaint Counsel's case on which it bears the burden of proof. *See Arch Coal*, 329 F. Supp. 2d at 116. As discussed *infra*, because the dynamics in the upstream market are critical to Complaint Counsel's theory of harm of foreclosure and raising rivals' costs, without properly defining the related product market, it cannot show that the merger is likely to "substantially lessen competition in the manner it predicts." *AT&T I*, 310 F. Supp. 3d at 194.

II. COMPLAINT COUNSEL FAILED TO PROVE THE TRANSACTION IS LIKELY TO SUBSTANTIALLY LESSEN COMPETITION.

Complaint Counsel's failure to prove its relevant and related product market allegations is not the only reason its challenge to the Transaction is untenable. Assuming, *arguendo*, the relevant and related markets were as Complaint Counsel imagines, its case still lacks merit because it is based on impermissible speculation. *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004) ("antitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future."). Such speculation cannot be the basis for proving that the Transaction is likely to substantially lessen competition, as is required to establish a claim under Section 7 of the Clayton Act. *AT&T I*, 310 F. Supp. 3d at 194, (to prove a violation of the Clayton Act, the Government must show that "notwithstanding the proposed merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger, "at this time and in this

remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts.").

The Transaction is a purely vertical merger. It is widely recognized that vertical mergers do not raise the same concerns as horizontal mergers because they do not involve the combination of substitutable products and the reduction of competition between them. It is also well established that vertical mergers often generate large efficiencies that benefit consumers, and that they can harm competition only in narrow circumstances. Thus, Complaint Counsel's challenge to this vertical merger cannot rely on any presumptions of harm that may be available in a horizontal case. As the Court of Appeals in *AT&T II* recognized, "unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share." *AT&T II*, 916 F.3d at 1032. Further, much more is required than "testimony from third-party competitors" that is "speculative, based on unproven assumptions, or unsupported." *Id.* at 1038 (quoting *AT&T I*, 310 F. Supp. at 214). Rather, Complaint Counsel was required to bring forward substantial evidence that the Transaction likely will result in competitive harm that outweighs the Transaction's procompetitive benefits. As discussed below, Complaint Counsel, by a wide margin, failed to carry its burden of proving likely competitive harm.

More specifically, Complaint Counsel's case falls short because it (1) is based on assumptions unsupported by a reliable economic model and out of step with economic reality; (2) fails to account for the fact that Illumina attempting to foreclose GRAIL's putative rivals would hurt Illumina's NGS sales and reputation; (3) disregards the fact that NGS costs are today a small part, and within the next few years will be a very small part, of MCED test revenues and

margins; (4) offers no basis to predict any material diversion to Galleri from the alleged foreclosure strategy; (5) overlooks viable alternatives to Illumina's NGS products for MCED development; (6) misunderstands Illumina's prior vertical integrations and (7) disregards the Open Offer (*see* Section III *infra*).

A. Complaint Counsel Based Its Case on Assumptions Unsupported By a Reliable Economic Model and Out of Step with Economic Reality.

As an initial matter, Complaint Counsel grounded its case on assumptions not evidence. Those assumptions are inconsistent with Complaint Counsel's burden, unsupported by a reliable economic model, and out of step with economic reality. Complaint Counsel effectively relies on a presumption against vertical mergers that finds no support in either the empirical evidence or the law. A case so grounded cannot stand.

1. Complaint Counsel Grounded Its Case On Assumptions, Ignoring Its Burden of Proof.

It is undisputed that there are no fewer competitors in any upstream market, or in any downstream market, as a result of the Transaction. Yet, Complaint Counsel contends this purely vertical merger will substantially lessen competition because, it says, the reunion of Illumina and GRAIL will give Illumina the ability and incentive to disadvantage GRAIL's putative rivals (should they ever launch an MCED test). In so doing, however, Complaint Counsel simply assumes away the existence of any efficiencies resulting from the Transaction, taking the position that the burden regarding efficiencies falls entirely on Respondents. That approach is inconsistent with Complaint Counsel's burden of proof in a vertical case.

While the burden shifting framework announced in *United States v. Baker Hughes Inc.*, 908 F.2d 981, 990–91 (D.C. Cir. 1990), may apply, it operates differently for vertical mergers than it does for horizontal mergers. In particular, a challenge to a vertical merger must be assessed in the light of the widespread recognition that, unlike horizontal mergers, "most

vertical mergers are procompetitive." 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 10A-1 (5th ed. 2021); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve.").[11]

Complaint Counsel thus bears the burden to demonstrate that the vertical merger at issue is anticompetitive when any resulting harm is balanced against any resulting efficiencies. The District Court of the District of Columbia applied this approach in *AT&T I*, the only vertical merger challenged by the DOJ in over four decades. 310 F. Supp. 3d 161. In rejecting the DOJ's challenge to the vertical merger at issue, the court in *AT&T I* observed that there is "recognition among academics, courts, and antitrust enforcement authorities alike that 'many vertical mergers create vertical integration efficiencies between purchasers and sellers.'" *Id.* at 193. The court described the government's burden under the *Baker Hughes* framework, explaining: "I will discuss the conceded consumer benefits associated with the proposed merger. Mindful of those conceded benefits, and the need to balance them against the Government's allegations of consumer harm, I will then evaluate whether the Government has carried its burden to show a likelihood that the challenged merger will result in a substantial lessening of competition." *Id*. at 195. As Dr. Carlton testified, "[i]f you don't take account of the efficiencies

[11] *See also* 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) ("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.").

or, more broadly, the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've failed to balance the benefits against the possible harms." (PFF ¶ 803.1.) Even the government's expert in AT&T acknowledged that such balancing was necessary. *AT&T I*, 310 F. Supp. 3d 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.").[12]

[redacted] Moreover, Complaint Counsel treated the elimination of double marginalization ("EDM") as an efficiency to be proven by Respondents instead of a unilateral pricing effect relevant to whether Complaint Counsel can establish its *prima facie* case, even though treating EDM this way generates inaccurate, upwardly biased (*i.e.*, government friendly) predictions of net upward pricing pressure and competitive harm. The Vertical Merger Guidelines, recently withdrawn on a partisan basis, required such balancing and rejected Complaint Counsel's

[12] It is well recognized by legal and economic antitrust experts that the government cannot meet its burden by ignoring efficiencies. *E.g.*, *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"); Bruce H. Kobayashi and Timothy J. Muris, *Screening Out Innovation—Vertical Merger Principles and the FTC's Misapplication in the Illumina-GRAIL Case*, Competitive Enterprise Institute (2021) (hereinafter, "Kobayashi & Muris").

approach by correctly treating both the downward pricing pressure associated with EDM and the upward pricing pressure associated with raising rivals' costs ("RRC") as part of a plaintiff's burden to show competitive harm. *See* Kobayashi & Muris, at 12.

2. Complaint Counsel Offered No Reliable Model.

To meet its burden, Complaint Counsel was required to present a model showing any anticompetitive effects of the Transaction outweigh its efficiencies. *See, e.g.*, *AT&T I*, 310 F. Supp. 3d at 237 (rejecting the government's challenge to the vertical merger for failure to meet "the Government's burden to adequately support its proffered [vertical theory of] harm"); *Fruehauf Corp. v. FTC*, 603 F.2d 345, 355, 360 (2d Cir. 1979) (rejecting the government's challenge to a vertical merger because its theories were based on "speculation rather than fact" with respect to one market and "too ephemeral" with respect to another market to prove that some degree of foreclosure would be sufficient to "significantly lessen" competition); *United States v. Hammermill Paper Co.*, 429 F. Supp. 1271, 1293–94 (W.D. Pa. 1977) (holding that "the United States has not carried its burden of proof that the effect of the [vertical] acquisition . . . may be substantially to lessen competition in the manufacture and sale of printing and fine paper in the United States" because "the possibility of foreclosure of access by manufacturers is barred by" a multitude of factors).

As Respondents' economics expert Dr. Carlton explained, "vertical merger analysis requires a complete model . . . that you quantitatively can use to balance all the various economic factors that arise in an industry", including efficiencies, profit margins at both stages of production, reputational and contractual constraints on the merged firm, demand curves, substitution patterns, diversion ratios and upstream competition. (PFF ¶ 802–803.) Ultimately, if the model does not "take account of the efficiencies, or more broadly the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've

failed to balance the benefits against the possible harms." (PFF ¶ 803.1.) The model must also take account of the "timing and magnitude of potential harm versus likely benefit" because "if the harms are far off in the future, but the benefits are closer in", that critical balance of potential harms versus benefits would be skewed and a procompetitive vertical merger could, as a result, be disallowed, depriving consumers of enormous benefits.[13] (PFF ¶ 805.)

[redacted] That is not enough to stop a life-saving transaction. The undisputed evidence showed that the Transaction will generate huge efficiencies, accelerating patient access to Galleri, at lower prices, resulting in thousands of lives saved with monetary benefits exceeding $35 billion. (PFF ¶ 1123.) [14]

While Dr. Scott Morton claims she has modelled the effects of the Transaction, her "model" is nothing more than a series of simplistic, and factually inaccurate, assumptions. In

[13] As a leading antitrust treatise explains, "there is no comparable theoretical basis for dealing with vertical mergers" as with horizontal mergers. 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1000a (5th ed. 2021). "[W]hether vertical mergers are likely to harm competition, and under what circumstances, are ultimately empirical questions." Gregory S. Crawford, et al, *AT&T/Time Warner and Antitrust Policy Toward Vertical Mergers*, CPI Antitrust Chron, 2, 3 (July 2019).

[14] "Unlike horizontal product mergers, in pure vertical product mergers, concentration in either the upstream or downstream markets remains unchanged, and any theoretical or empirical link between structure and effects are limited to nonexistent. Thus, the same structural evidence relevant to evaluate horizontal product mergers does not allow inferences about the likely effects of vertical product mergers. This limitation applies *a fortiori* to vertical innovation mergers, as any theoretical or empirical relationship between vertical structure and innovation is more tenuous than in a horizontal innovation merger or a vertical product merger." Kobayashi & Muris, at 3.

particular, she assumes, against the evidence, that Illumina faces and will face no upstream competition, and that Illumina's reputation and contractual commitments do not and will not constrain Illumina's purported incentives and ability to harm its customers. None of these assumptions is valid, and beyond that, her model does not reflect *any* efficiencies—meaning, according to Dr. Scott Morton, the Transaction, which has undeniable life-saving and other benefits, will be the very rare vertical merger to generate *no* merger-specific efficiencies at all. That is facially incredible and is refuted by the uncontroverted evidence. [redacted] Their failure to put forward a full model of the effects of the Transaction is fatal to Complaint Counsel's challenge of the Transaction.

Furthermore, to demonstrate "the probable anticompetitive effect of the merger" Complaint Counsel must show that Illumina's likely incentives absent the transaction would be different, or else there could be no merger-specific "effect". *AT&T I*, 310 F. Supp. 3d at 190 (internal quotations omitted). In other words, Complaint Counsel must prove that the Transaction will change the *status quo* to a large enough extent to substantially lessen competition. Complaint Counsel's showing fails here as well. It is undisputed that, absent the Transaction, Illumina would have a 12% stake in GRAIL's profits and would receive 7% of GRAIL's net revenues (a royalty) on every sale. (PFF ¶ 816.) The royalty is a unique feature of GRAIL's contract with Illumina, reflecting Illumina's contributions to the formation of GRAIL; Illumina has no comparable arrangement with any other test developer purportedly developing an MCED test. (PFF ¶ 817.) Every incentive that Complaint Counsel speculates Illumina might have after the Transaction was *already in place* before the Transaction was consummated. Thus,

under Complaint Counsel's own theory of Illumina's incentives, Illumina "makes much more money if a customer uses the GRAIL test than if it uses that of" a GRAIL rival, which means "there already is an incentive to favor GRAIL" and "therefore, the merger" has no effect on Illumina's dealings with GRAIL's putative rivals. (PFF ¶ 818.) [redacted] She attempts to obscure the issue simply by assuming that, absent the Transaction, Illumina would charge royalties to GRAIL's putative rivals that would be at least as large as the royalties Illumina was contractually entitled to receive from GRAIL. But this is a wholly baseless assumption that ignores the unique nature of the GRAIL royalty, and the undisputed fact that no other supply agreement contains such a provision. (PFF ¶ 821.) Complaint Counsel and its expert cannot simply make up facts that are the exact opposite of the relevant real-world facts to prove anticompetitive effects arising from the merger. By electing not to conduct a proper analysis of Illumina's incentives with and without the merger, taking into account the relevant real-world facts, Complaint Counsel failed to prove a "probable anticompetitive *effect of the merger*". *AT&T I*, 310 F. Supp. 3d at 190 (emphasis added).

At bottom, Complaint Counsel neglected to incorporate basic facts and economic concepts into its case, "choosing to rely solely on speculative harms, distant in time and therefore heavily discounted, while simultaneously ignoring closer in time benefits with more empirical support." Kobayashi & Muris, at 5. To quote a former Chair of the FTC and a former Director of the FTC's Bureau of Economics:

> "[t]he implications for antitrust law are therefore stark. If the Complaint Counsel's approach is adopted, we see no limiting principle to prevent the FTC or

> any antitrust plaintiff from asserting the possibility of theoretical future harm unsupported by evidence as a sufficient basis for enjoining a vertical merger. Adoption of this approach would impose a de facto per se prohibition of vertical mergers whenever the FTC perceives the upstream firm as dominant and theoretically capable of foreclosure at some future time."

Kobayashi & Muris, at 5. Put differently, Complaint Counsel effectively asks the Court to adopt a presumption against vertical mergers, though "no body of empirical evidence" supports such a presumption (based on structure or any other grounds)", Kobayashi & Muris, at 2, and the law is clear that Complaint Counsel bears the burden to prove the Transaction unlawful, *AT&T I*, 310 F. Supp. 3d at 194; *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020).

3. Complaint Counsel's Failure to Account for the Open Offer Is Out of Step With Economic Reality.

In addition to relying on unfounded assumptions instead of a reliable economic model, and failing to prove a change in the *status quo* resulting in substantially lessened competition in light of Illumina's pre-merger economic stake in GRAIL, Complaint Counsel's approach ignores the economic reality of the Open Offer, further defying decades of precedent.

Evaluating the effect of any merger requires consideration of its effect on competition, which necessarily entails consideration of the economic reality. *See, e.g.*, *AT&T II*, 916 F.3d at 1038 (holding that "the government had not met its first-level burden of proof" as "[n]either the model nor Professor Shapiro's opinion accounted for the effect of the irrevocably-offered arbitration agreements, which the district court stated would have 'real world effects' on negotiations"); *FTC v. Libbey*, 211 F. Supp. 34, 46 (D.D.C. 2002) (criticizing the FTC for predicating its request for an injunction on the terms of an original merger agreement rather than the amended agreement). Yet here, neither Complaint Counsel nor its expert properly took account of the Open Offer in balancing the alleged harms of the Transaction against its demonstrated efficiencies. They simply dismissed the Open Offer as a conduct remedy that they

deemed insufficient by itself to alleviate their concerns about the Transaction. While Complaint Counsel erred in dismissing the Open Offer as a viable "remedy" (as is discussed in Section III below), that is a different matter from the Open Offer's impact on likely real-world effects of the Transaction as mandated by the Clayton Act. Complaint Counsel failed altogether to factor the Open Offer into the assessment of the Transaction's likely real-world effects, instead taking the position that the Open Offer can be analyzed merely as a remedy to a proven anticompetitive merger. However, the Open Offer is a binding contractual commitment, just as Illumina's customer supply agreements are binding commitments and, therefore, real-world facts that impact Illumina's incentives and constrain Illumina's conduct. As such, Complaint Counsel was required to account for the effects of the Open Offer, just as it as required, as part of its prima facie case, to account for all relevant, real-world economic facts to demonstrate that the Transaction will likely result in foreclosure of competition. *See Arch Coal*, 329 F. Supp. 2d at 159 ("[T]his Court's task [is] . . . to review the entire transaction in question . . . [and] the Court is unwilling simply to ignore the fact" of the defendant's post-merger transaction commitment). This is especially true in a vertical merger where the government is required to make a fact specific showing of anticompetitive harm. As the Court of Appeals in *AT&T II* observed, the government has previously recognized that, "especially in vertical mergers, that conduct remedies . . . can be a very useful tool to address the competitive problems while preserving competition and allowing efficiencies that may result from the transaction." *AT&T II,* 916 F.3d at 1041 (internal quotations omitted). And where an irrevocable offer to customers guaranteeing fair treatment is made by the merging firm, the government's speculative claims of changed incentives, without taking that offer into account, become "largely irrelevant". *See id.* at 1046–47 (noting that "the government failed to meet its burden of proof" in part because DOJ's expert

had not considered the effect of offers of arbitration agreements). Thus, Complaint Counsel's challenge to the Transaction fails for yet another reason: it is divorced from the actual economic realities impacting Illumina's incentives and conduct in the real world.

* * *

In sum, Complaint Counsel rested on assumptions and speculation, rather than evidence and analysis, despite that "the economic literature, existing legal framework, and history of government merger enforcement show that the evaluation of vertical mergers requires a careful and evidence-based weighing of opposing effects." Kobayashi & Muris, at 3. As a former Chair of the FTC and a former director of the FTC's Bureau of Economics recently observed, the potential effect on consumers is striking:

> "A primary reason for the vertical merger between Illumina and GRAIL is to ensure that Illumina's substantial resources and expertise accelerate the commercial use of GRAIL's Galleri Multi-Cancer Early Detection (MCED) test. The FTC's Administrative Complaint notes that MCED tests 'can potentially avert [approximately] 100,000 cancer-related deaths' for each year of testing. Whether one simply counts the number of excess deaths that elimination of even a short delay in using GRAIL's first-to-market MCED test would avoid, or whether one ties these excess deaths to economic calculations based on the value of a statistical life, the near-term consumer gains from avoiding these excess deaths likely will dwarf the present value of any losses from the speculative decreases in price competition years in the future. Furthermore, consumers who would most benefit from the near-term effects of this merger will achieve no benefits from the FTC's actions. The thousands of individuals whose lives would be saved if the merger succeeds will not be alive to benefit from 'more competition' in some distant future."

Kobayashi & Muris, at 5 (citations omitted).

B. Complaint Counsel's Foreclosure Theory Fails, Because There Is No Basis To Predict Any Material Diversion to Galleri from the Alleged Foreclosure Strategy.

In addition to its dependence on assumptions that are unsupported by a reliable economic model and inconsistent with economic reality, Complaint Counsel's foreclosure theory founders because Complaint Counsel offered no basis to conclude that foreclosing GRAIL's

putative rivals would result in any material diversion of their sales to Galleri. Significant diversion is a necessary condition for a vertical merger to give rise to foreclosure incentives. As a matter of basic economics, "if there's no diversion, then there's no incentive to engage in [a foreclosure] strategy because the vertically integrated firm would just lose sales" and therefore "you need significant diversion for the strategy to make sense." (PFF ¶ 823.)

1. Complaint Counsel Failed to Prove Diversion.

Not only are there no sales to divert, but there also is substantial uncertainty around the MCED tests in development such that it is impossible to conclude that, if and when

they launch, the products will be sufficiently similar to Galleri that any increase in their costs would divert any material volume of sales to Galleri. To the contrary, most of the MCED developers cited by Complaint Counsel are planning to launch their products as single-cancer tests, [redacted] None of them has even ascertained the specific features of any MCED test that they may launch in the future [redacted], although it is clear that none is on a path to launching a test, like Galleri, that can detect more than 50 cancer types and cancer signal of origin in a single blood draw:

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]

More generally, Complaint Counsel presented no evidence that anyone would switch to any of the above tests from Galleri (or vice versa) or what price differentials would affect such switching.

Having failed to prove that the MCED tests in development will be close substitutes to Galleri, Complaint Counsel failed to prove that a foreclosure strategy by Illumina would cause material diversion from purported GRAIL's putative rivals, without which it cannot establish that the transaction would give Illumina an incentive to harm those purported rivals. *See HTI Health Servs v. Quorum Health Grp., Inc.*, 960 F. Supp. 1104, 1136 (S.D. Miss 1997)

(rejecting the plaintiff's diversion theory because the "testimony and expert opinion regarding a potential shift in patient admissions to ParkView is conjecture that is based on an assumption lacking in evidentiary support"); *Crouse-Hinds Co. v. InterNorth, Inc.*, 518 F. Supp. 416, 433 (N.D.N.Y. 1980) (rejecting the plaintiff's foreclosure claim because of the "limited evidence adduced by plaintiff . . . to even give a rough estimate of the degree of foreclosure" and "the statistics that . . . [did] not indicate . . . a substantial foreclosure").

2. Galleri is Highly Differentiated.

There is no basis to predict that Illumina would gain from a purported raising-rivals-costs strategy because the downstream rivals' future products are highly differentiated from Galleri. And, "if products are very different from one another, it suggests that they're unlikely to be close substitutes, and if they're not close substitutes, then the diversion of sales from the rival—to in this case GRAIL . . . [is] likely to be low or nonexistent", and "if it's low or nonexistent, then the incentive – the profit incentive to engage in the raising rivals' cost strategy . . . will also be low or nonexistent". (PFF ¶ 826.) [redacted]

While there is no way to know precisely what the MCED tests-in-development will look like (*e.g.*, what handful of cancers they will eventually be able to test for, if they are successful at all, and with what specificity and sensitivity), if and when they are launched, the available evidence makes clear they will not be close substitutes for GRAIL's Galleri test. On the contrary, given the vast differences between what we know about those tests and Galleri, it is clear that they will be too dissimilar to permit a foreclosure strategy to divert material sales to

Illumina from GRAIL's putative rivals. Galleri, which can detect more than 50 cancer types and show cancer signal of origin, all from a single blood draw, is truly in a class by itself. The next-closest NGS-based approach is Exact/Thrive's CancerSEEK, but the only form of that test that has gone through clinical trials (a) detects only 10 cancer types, (b) requires two separate blood tests, and (c) requires an invasive and risky PET/CT scan to identify tissue of origin in positive cases. [redacted] CancerSEEK is also unable to detect several cancers that Galleri has detected. (PFF ¶ 430.1.) The other supposed "competitors" to GRAIL are all working on tests that, if and when launched, will detect just one, two, or a small subset of the cancers Galleri can detect. Put simply, a test that detects only colon cancer, or only lung and liver cancer, is not substitutable for a test that screens for more than 50 cancer types. Although there are applications for single-cancer tests, especially if they are optimized for sensitivity in high-risk populations, there is no plausible scenario in which such tests are considered substitutable with a 50-cancer screening test. Differences between those tests in development and Galleri that make material diversion between them implausible include the number of cancers detected, whether the cancer types detected have existing standard of care screening options, whether the test requires a single test or multiple tests, the ability to detect tissue of origin, sensitivity, and specificity. We discuss each in turn.

Number of cancers detected. Galleri differs from the MCED tests-in-development based on the number of cancers that can be detected. [redacted]

Exact/Thrive's data shows only that its CancerSEEK assay can detect whether a patient has one of 10 types of cancer and is unable to identify which one without further invasive testing in the

form of a PET-CT scan. [redacted]

[redacted] The published Singlera

data is from a small, 418-sample case control study and shows only that Singlera's PanSeer assay potentially could detect five types of cancer. (PFF ¶ 839.8.)

Number of Tests Performed. Galleri differs from the MCED tests-in-development based on the number of tests of which it is comprised. Galleri consists of a single blood draw, whereas some of the tests in development actually comprise a series of tests. (PFF ¶ 840.) For example, Exact's CancerSEEK test, which Complaint Counsel argues is the closest potential substitute to Galleri, is actually three separate tests as of its latest published trial: two blood draws and a PET-CT scan. (PFF ¶ 840.1.) [redacted]

Cancer Signal of Origin. Galleri also differs from the MCED tests in development based on its ability to determine cancer signal of origin. (PFF ¶ 841.1.) [redacted]

[redacted]

Galleri is able to detect cancer signal of origin; that is, for positive cases, the test reveals where the detected cancer is likely located using the same blood sample that was analyzed to detect the cancer's presence. (PFF ¶ 841.1.) No other putative MCED test-in-development has demonstrated this capability. (PFF ¶¶ 684.2, 841.2.) For example, Thrive's CancerSEEK cannot detect tissue of origin and instead requires a diagnostic full-body PET-CT scan both to confirm the results of the blood testing—*i.e.*, that cancer has in fact been detected—and also to localize the potential cancer. (PFF ¶ 841.3.) Similarly, Singlera has said that any patient testing positive would then undergo additional blood testing and/or follow-up imaging to detect cancer signal of origin. (PFF ¶ 841.4.) [redacted]

Sensitivity. Galleri differs from the purported MCED tests-in-development based on its degree of sensitivity, often a test correctly returns a positive result to a patient who has the condition being tested for. (PFF ¶ 172.) Low sensitivity leads to high *false negative* rates. (PFF ¶ 172.) [redacted]

[redacted]

[redacted] As shown in the table below, the sensitivity of the MCED tests to which Complaint Counsel points for which there is any data are very different from sensitivities for the cancers detected by Galleri.

Specificity. Galleri also differs from the MCED tests in development based on its degree of specificity, meaning how often a test correctly returns a negative result to a patient who does not have the condition being tested for. (PFF ¶ 173.) Low specificity leads to high *false positive* rates. (PFF ¶ 173.). [redacted]

Existing Standard-of-Care Protocols. Further, most of the putative tests-in-development are focused on cancer types with existing standard-of-care screening protocols (PFF ¶¶ 482, 701–705), for which a high sensitivity is necessary but a lower specificity is acceptable given the ability to turn to standard-of-care screening to assess whether a positive case is a true positive. [redacted]

[redacted]

And as the table below also shows, the specificity of the MCED tests-in-development on which Complaint Counsel relies, for which there is any specificity information in the record, is very different from the specificity measured for Galleri.

Table 7

Test	Galleri (GRAIL) 1 Blood Test	CancerSEEK (Exact/Thrive)			PanSeer (Singlera) 1 Blood Test
		1 Blood Test	2 Blood Tests	2 Blood + PET-CT	
Study	CCGA3	DETECT-A			Taizhou L.S.
Types of Cancer	50	10			5
Cancer Signal of Origin	Yes	No	No	Yes	No
Specificity	99.5%	95.3%	98.9%	99.6%	96.1%
Sensitivity	51.5%	30.2%	27.1%	15.6%	94.9%
PPV	44.4%	5.9%	19.4%	28.3%	

(PFF ¶ 843.4, Table 7.)

[redacted]

[redacted] Similarly, Galleri outperforms CancerSEEK by a significant margin in terms of its positive predictive value: when extrapolating to the general screening population, Galleri would detect over 44% of positive cases, while CancerSEEK would detect just over 28%—and would need the aid of a PET-CT scan to do so. (PFF ¶ 725.)

The only medical experts who testified during the administrative proceeding agree that Galleri is very different from the MCED tests in development, and that those differences matter to whether the different tests would be viewed as close substitutes by the marketplace. (PFF ¶ 844.) [redacted] Dr. Cote opined that other MCED tests in development would not be substitutes for Galleri, both because of their inability to detect cancer signal of origin, as well as other performance metrics such as sensitivity and specificity. (PFF ¶ 844.2.) [redacted]

[redacted]

Complaint Counsel's failure to prove material diversion is a fatal flaw in its case because "to identify and analyze [any] input foreclosure theory . . . [t]he key metric . . . is the diversion ratio from . . . downstream rivals to the merged entity". Carl Shapiro, Testing Vertical Mergers for Input Foreclosure, Organization for Economic Co-operation and Development (2019) (Figure 3 showing that if diversion is insignificant, a merger should be cleared)).

[redacted]

3. Complaint Counsel's Dismissal of Differentiation is Baseless

Complaint Counsel and Dr. Scott Morton speculate that current differentiation does not matter because they say the tests in development can easily and swiftly jump from single- or few-cancer tests to 50-cancer tests. But attorney argument and an economist's speculation cannot outweigh the uncontested evidence to the contrary. *See Aerotec Int'l, Inc. v. Honeywell Int'l, Inc.*, 836 F.3d 1171, 1175 (9th Cir. 2016) ("[A]necdotal speculation and

supposition are not a substitute for evidence"); *see also Arch Coal*, 329 F. Supp. at 117 ("[A]ntitrust theory and speculation cannot trump facts").

As Dr. Aravanis—one of the few witnesses at trial who has ***actually developed*** a screening test for 50-cancer types—explained, expanding a single cancer test to a 50-cancer test is not a viable approach to developing a test like Galleri. For each cancer included in an MCED like Galleri, you "have to go through a somewhat similar process to what GRAIL did", meaning "a research phase", "a test development phase", and "a clinical phase", and that must be done "for each cancer", which, if done "serially" would take a "very long time" and is "not practical". (PFF ¶ 846.1.) Dr. Aravanis further explained that it is not "straightforward to expand [a single cancer test] to all other cancers" because **"**to develop a test for a new indication, like a new cancer, you have to go get samples related to that different cancer. You have to find the signals. Then you have to develop a technology for that. Then you have to do [the] relevant clinical trial. There's no shortcut. . . . [T]here's hundreds of diagnostics developed" and "I've never heard of an example where because you developed a test for one thing, you can now—it's a shortcut to develop a test for something different." (PFF ¶ 846.2); *see supra* Section I.A.2.)

Similarly, Dr. Cote testified that developing a single-cancer test does not put a test developer "in a position where they're ahead in developing a cancer screening test for a different cancer" because the "development of biomarkers for a particular cancer will not be adequate for other cancers" and, for each cancer, the developer must "go through the case-control verification to determine whether or not the assay has the performance characteristics needed for . . . the new target cancer, and then has to go through a prospective trial depending on which cancer is being targeted"—a process that can take years and with no certainty of a successful outcome. (PFF ¶ 846.3.) Complaint Counsel's claim that third-party tests-in-development will become Galleri-

like in the foreseeable future is wishful thinking and inconsistent with diagnostic product development protocol, methodology, and experience. (PFF ¶¶ 846.2–846.3.)

[redacted] However, Dr. Abrams, the only expert primary care physician to testify in this case, explained that the ability to detect tissue of origin is a key differentiating feature that will influence physician and patient choice. (PFF ¶ 841.10.) [redacted] Thus, Dr. Scott Morton and Complaint Counsel offer no basis to ignore the evident, significant differentiation between Galleri and other tests in development, and the only expert testimony in the record explaining that, in light of that differentiation, material diversion between Galleri and the other purported MCED tests in development is unlikely.

C. Complaint Counsel Failed to Account for the Impact Any Attempted Foreclosure would have on Illumina's NGS Sales and Reputation.

Further undermining Complaint Counsel's case is the fact that Complaint Counsel's theory of harm does not account for the impact of an attempted foreclosure strategy on Illumina's upstream sales and reputation. *See, e.g., AT&T I* 310 F. Supp. 3d at 243–44 (rejecting

the government's vertical foreclosure theory because "it would be 'profitable' for the merged entity to continue to license [upstream] Time Warner content to [downstream competitors] virtual MVPDs"); *Fruehauf Corp. v. FTC*, 603 F.2d 345, 354 (2d Cir. 1979) (rejecting the Commission's assumptions of vertical foreclosure and diversion because upstream supplier, Kelsey, "would risk [customers'] retaliating by shifting to competing suppliers not only their purchases of [Heavy Duty Wheels] but of other products presently bought from Kelsey, which could cause it greater economic harm"); *HTI Health Servs. Inc. v. Quorum Health Grp., Inc.*, 960 F. Supp. 1104, 1137 (S.D. Miss. 1997) (rejecting the plaintiff's vertical foreclosure theory because "any financial incentive or alleged ability on the part of the [upstream] Vicksburg Clinic physicians to shift patients to [downstream] ParkView is negated by" "a countervailing economic incentive . . . to maintain a cooperative association with [ParkView's competitors]").

1. Any Attempted Foreclosure Would Cost Illumina Profitable Upstream Sales.

Illumina's core business consists of selling NGS instruments and consumables. Illumina's NGS products comprise the vast majority (more than 90%) of its revenues and profits. (PFF ¶ 22.) Illumina's NGS business is expected to be the dominant driver of Illumina's profits well into the future:

- As Mr. deSouza explained, "[t]he vast majority of Illumina's revenue in the next ten years will come from our sequencing business, our sequencers and consumables." (PFF ¶ 849.1.) Because Illumina's "core business is to sell sequencers and consumables", its "strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve." (PFF ¶ 849.1.)

- Dr. Aravanis similarly testified that "Illumina's business is based on growing sequencing markets" by "lowering the cost, allowing people to do more sequencing" and "has also been driven by new applications that are developed", and "Illumina is hoping for more of those applications to be developed" on its platforms, which creates "a strong incentive for us to continue to decrease cost, and that's our plan." (PFF ¶ 849.2.)

- Dr. Goswami testified that the majority of Illumina's revenues come from NGS tools, and the Transaction "keeps our commitment to delivering NGS solutions to the broad sector of customers we serve." (PFF ¶ 849.3.)

Complaint Counsel did not offer any evidence to the contrary. Complaint Counsel's foreclosure argument as to what might happen 10 or more years from now is mere conjecture. *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116 (D.D.C. 2004) ("antitrust theory and speculation cannot trump facts").

Any attempt by Illumina to foreclose GRAIL's rivals would harm Illumina's core NGS business, because it would result in the loss of highly profitable NGS sales in MCED and non-MCED applications. [redacted] Those sales either would divert to rival sequencing platforms, such as those that are currently available or are in active development described above, or they would dissipate because customers would respond to foreclosure by choosing to no longer invest in NGS applications on Illumina systems. [redacted] In either case, the loss to Illumina would be enormous—unless, contrary to fact, Illumina was assured of recouping a substantial volume of the resulting lost in profits through diversion to GRAIL. (PFF ¶ 850.2.)

[redacted] Yet, Dr. Scott Morton admitted that she did not quantify the per-test gross profits Illumina earns from selling sequencing products used by any hypothetical MCED rival for non-screening tests. (PFF ¶ 852.) Nor did she calculate the gross profits that Illumina would lose if, as a result of attempted foreclosure of an MCED test developer, the test developer moved all of its tests, including non-MCED tests, to a different platform. (PFF ¶ 852.) As Mr. deSouza explained, "if we [raised prices] we would lose [our

customers'] business. They would move on to . . . a BGI or a Thermo", that is, Illumina would lose upstream revenues it earns today and expects in the future both from MCED developers and other customers. (PFF ¶ 850.3.) Dr. Febbo similarly confirmed that attempted foreclosure would "really disincentivize an R&D lab or clinical labs from using our platforms, which would have a major impact on our business" through lost NGS sales. (PFF ¶ 850.4.)

2. Any Attempted Foreclosure Would Inflict Significant Reputational Harm on Illumina.

Illumina has cultivated a reputation as a trusted supplier of NGS technology. Illumina has developed its reputation by investing substantial amounts into innovation and dramatically lowering sequencing costs over time. (PFF ¶ 853.) Today, Illumina's brand is synonymous with innovative, low-cost sequencing systems. (PFF ¶ 855.) The phenomenon of dramatically declining sequencing costs is known in the industry as "Flatley's law", referring to Jay Flatley, Illumina's former CEO and Chairman. (PFF ¶ 855.2 ("'Flatley's law' was a term coined by . . . a writer in Forbes magazine when he wrote an article comparing the reduction in the price of sequencing to Moore's law, which describes the reduction in the price of like silicon wafers or something in the computer industry, and [under Jay Flatley's] leadership where we really drove significant, significant reductions in the price of sequencing . . . down towards the level that they are today.").)

Both Illumina witnesses and third parties attested to Illumina's long-standing reputation for innovation and driving down sequencing costs. In a sworn declaration to the FTC, an Illumina oncology customer (Invitae) stated that "Illumina's role as an innovator in NGS has moved the field forward tremendously, as they have constantly and steadily reduced sequencing costs over time." (PFF ¶ 856.1.) Gary Gao of Singlera testified that Singlera is "very happy Illumina has paved the way for NGS" and that he credited "the Illumina team for leading a

genome revolution". (PFF ¶ 856.2.) Ms. Berry explained that Illumina routinely measures its reputation using "net promoter score" customer surveys, a widely-used survey methodology, and frequently receives "very high Net Promoter Scores relative to industry benchmarks." (PFF ¶ 856.3.)

Illumina's reputation for NGS innovation and lowering sequencing costs is critical to the continued success of Illumina's NGS business and overall profitability:

- Illumina's profits from clinical applications are largely in the future. (PFF ¶ 857.1 ("even with all the progress we've made in the last . . . almost two decades since the first human genome, today we still understand very little of how your genome translates into health and disease states. . . . There is a lot of research going on in that area, and once the researchers uncover the connections between your genome and those conditions, we'll start to see clinical applications emerge to do the testing based on that finding. . . . [W]e have so much undiscovered in front of us. As we discover that, I have no doubt we will see a lot more clinical applications emerge in the future."); PFF ¶ 857.1 (NGS is still in the "early days" as a "tool for clinical diagnostics", and there are "many new applications emerging, and some of those could be even bigger than the ones we have today"—it is "still early in seeing how [NGS] can benefit medicine.");

- Illumina relies on its customers to invest in costly R&D to generate demand for Illumina's products, including in applications that have not yet been developed or possibly even conceived (PFF ¶ 857.2 ("Our mission remains to . . . enable all attributes of our technology to drive accessibility and utilization across as many use cases as possible, and certainly pricing is a key element of that, a key enabler of that, and so continuing to drive down the price of sequencing is something that we are absolutely relentlessly continuing to pursue.");

- To realize those future profits, Illumina must incentivize customers to invest, which requires that Illumina maintain its reputation as a supporter of innovation by its customers in products that use Illumina's NGS technology. (PFF ¶ 857.3.)

Critically, Illumina cannot predict which of its customers will create the next breakthrough product that will greatly expand the adoption of NGS. (PFF ¶ 857.5.) Illumina thus has the incentive to support all of its customers, even if Complaint Counsel were right that foreclosure could result in short term gain. (PFF ¶ 857.7.)

Complaint Counsel's theory of harm overlooks that an attempted foreclosure strategy would cause substantial harm to Illumina's reputation. [redacted] The unrefuted evidence showed that if Illumina attempted to foreclose cancer screening test developers, its reputation would change from a supporter of clinical development on its platforms to a supplier willing to engage in opportunistic hold-up when the applications it encourages customers to develop reach scale and profitability. [redacted] Such a reputation would damage Illumina's NGS business and harm its expectation of future profits from the expansion of NGS-based clinical testing. (PFF ¶ 859.) Many innovative customers would choose not to invest in developing emerging and future applications using Illumina's platforms—not just limited to cancer screening—opting instead to pursue such applications on rival upstream platforms, or not at all. [redacted] This in turn would stunt the growth and expansion of Illumina's NGS products to new applications and diminish Illumina's future sales in markets in which GRAIL is not active, making recoupment of those lost sales impossible even under Complaint Counsel's theory of diversion. [redacted] The reputational damage from an attempted foreclosure strategy would also harm Illumina by making it difficult to attract and retain the best scientists and innovators. (PFF ¶ 863.) As Dr. Aravanis explained, "many employees come to Illumina because of our culture and our values" and "impeding innovation would be counter to that" and make it difficult to "retain[] the talent we have and attract[] new people who want to work on developing new sequencing technology applications." (PFF ¶ 863.)

Illumina's witnesses offered uncontested evidence that an attempted foreclosure strategy would substantially harm Illumina's reputation and, in turn, Illumina's future NGS growth and profitability:

- As Dr. Aravanis explained, attempting to foreclose a GRAIL rival "would be very detrimental" because "our business is based on customers using our platforms for

their applications, developing new applications" and "[w]ere we to do something like foreclose on a customer's business . . . we would jeopardize the existing customer relationships", and "at a kind of reputational level, to do something like that . . . is not consistent with our mission and values." (PFF ¶ 864.1.)

- Dr. Febbo explained: "[I]f we were to behave in a way that precluded competition or in a way that disincentivized groups to use our sequencing and screening, that would disincentivize other companies, laboratories from early research and development through the development of clinical tests from using our platform and, thus, it is in our best interest to make sure that we continue to create an environment where laboratories are excited to use our platform to develop screening tests for cancer, as well as all the other applications we see happening." (PFF ¶ 864.2.)

- Mr. deSouza explained: "[I]f people heard that we were raising costs in a market, I mean, that would cause us to have a ripple effect of losses in our sequencer business, not just in the cancer screening market, not just in the oncology market, but across our customer base as a whole." (PFF ¶ 864.3.) Mr. deSouza further noted that the reason it is "very important for us that our customers . . . recognize that we are the company that drives the cost of sequencing down at high quality and makes sequencing more accessible" is because we would lose their business. They would move on to, you know, a BGI or a Thermo", and for Illumina it is important to remain known as the company "that drives prices down" and "encourages an ecosystem even in markets where we have a test." (PFF ¶ 864.3.)[15]

The expert evidence is in accord. From an economic perspective, it is critical to consider a firm's reputation in analyzing that firm's incentives and ability to foreclose its customers following vertical integration. (PFF ¶ 866.) [redacted]

[15] Complaint Counsel suggested that Illumina's reputation is not valuable to Illumina because, in its SEC disclosures, Illumina noted that its decision to close the Transaction could have potentially adverse consequences to Illumina's reputation. (PFF ¶ 865.) However, Mr. deSouza explained that, although there is *a risk* of reputational harm that has to be disclosed, Illumina believes that "once people hear what we did . . . there won't be damage to our reputation" given the reasons for closing and the impact of the Transaction on cancer care and saving lives. (PFF ¶ 865.) In other words, Mr. deSouza, and Illumina, believe that closing the Transaction will *in fact* have a positive impact on Illumina's reputation. (PFF ¶ 865.1.) Also, there is nothing in the SEC disclosure that suggests that closing the Transaction would harm Illumina's reputation for lowering costs and innovating to encourage development on its platforms—and it is *that* reputation that an attempted foreclosure strategy would undoubtedly injure. (PFF ¶ 865.2.)

[redacted] The unrefuted evidence shows that Illumina's reputation constrains its incentive and ability to foreclose any GRAIL rival, because Illumina's customers are "investing large amounts of money right now in the hopes of having profitable products in the future", but "[i]f Illumina got a reputation for either jacking up price when someone's successful or harming them in some other way, that would have implications for the willingness of customers to continue to do business with Illumina as they're doing now." (PFF ¶ 866.2.) If Illumina "did start raising rivals' costs, its reputation for doing that would become known, and Illumina's customers now, as well as future customers, would be reluctant to do business with Illumina because they wouldn't want to make these huge investments if they think that Illumina is going to take advantage of them in the future". (PFF ¶ 866.3.) "Illumina's strategy of having customers who are inventing new uses for Illumina's NGS technology would be upended, and that would have negative consequences for Illumina and its profits." (PFF ¶ 866.4.)

3. Complaint Counsel Failed to Demonstrate Any Offsetting Advantage to Foreclosure.

In view of the impact foreclosure would have on Illumina's sales and reputation, the only way Illumina could have an incentive to foreclose GRAIL's putative rivals—whether by attempting to cut off their supply of Illumina NGS products, raising their costs, withholding services, or otherwise—is if such foreclosure diverted enough sales from those putative rivals to GRAIL to recoup all the losses resulting from the damage foreclosure would cause to Illumina's upstream sales and reputation. *See, e.g.*, *AT&T I*, 310 F. Supp. 3d at 251; *HTI Health Servs*, 960 F. Supp. at 1136–37; *Fruehauf*, 603 F.2d at 359.

Complaint Counsel failed altogether to show that the revenue and reputational losses that Illumina would incur by foreclosing GRAIL's putative rivals would be offset by any additional profits it would make from rival sales diverted to Galleri. It made no effort to quantify

Illumina's lost NGS sales, the value of harm to its reputation, or the sales it would pick up from GRAIL's putative rivals. As noted above (Section II.B), Complaint Counsel offered no evidence that *any* sales would be diverted to Galleri, no evidence that substitution would occur, and no evidence of price effects—much less that diversion would be of such a magnitude that it would make up for certain upstream losses. Thus, Complaint Counsel failed to meet its burden, which cannot be satisfied with speculation. *AT&T*, 310 F. Supp. 3d at 251 (rejecting the government's vertical foreclosure theory because the government offered insufficient evidence to show "that HBO promotions [the upstream products] [were] so valuable that withholding or restricting them [would] drive customers to AT&T [the downstream firm]"); *HTI Health Servs., Inc.*, 960 F. Supp. at 1136 (finding no foreclosure because there was "no credible evidence that postmerger financial incentives [would] cause the Vicksburg Clinic physicians [upstream suppliers] to shift their hospital patient admissions to ParkView [downstream firm]" away from ParkView's competitors); *Fruehauf*, 603 F.2d at 359 (rejecting the FTC's vertical foreclosure theory in part because the Commission erroneously assumed that the upstream firm would "divert to" the downstream firm "sales that would otherwise be made to other consumers").

[redacted] As Mr. DeSouza explained, "the testing business for many, many years

will not have a profit, will lose business, and that's very typical in clinical testing businesses". (PFF ¶ 869.) [redacted] It is only "after 2026" that Illumina gets "its first dollar of profit" from GRAIL, but "it's not until 2030 where we've recouped the losses we've made in GRAIL", and therefore, "about the next decade even, we really need and are really fueled by the profit pools associated with our sequencers." (PFF ¶ 871.) Thus, the uncontested evidence shows that Illumina's NGS business will remain its core business and will account for most of its profits for "many, many years". (PFF ¶ 872.) And the uncontested record evidence shows that there will likely be many alternatives to Illumina's NGS sequencers by that time. (*See* Section I.B *supra*.)

Complaint Counsel argued that Illumina can avoid losing sales and hurting its reputation because it will be able to identify and specifically target (as part of a foreclosure strategy) tests that are rivals to Galleri, limiting the damage to its upstream business. However, Complaint Counsel cannot explain how (and has not shown that), even if it were feasible to target specific tests as part of a foreclosure strategy, doing so would not result in severe reputational harm and upstream losses for Illumina. The evidence is to the contrary, as explained below. Further, Complaint Counsel has not shown that Illumina is capable of targeting only MCED tests that are rivals to GRAIL as part of a foreclosure strategy. Although Illumina may have an understanding of the general types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (PFF ¶¶ 873–873.1.) Nor does Illumina know the specific attributes that would allow it to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a

market-expanding complement— foreclosure of which could cause no material diversion to Galleri (even under Complaint Counsel's diversion theory) but would surely result in lost upstream sales. (PFF ¶¶ 873–873.1.) 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". (PFF ¶ 875.1.) 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.

Even if Illumina hypothetically could target a particular MCED test in development, news of Illumina's opportunistic conduct would reduce future sales to a range of applications, not just the targeted MCED test. (PFF ¶ 877.) As Mr. deSouza observed:

> "[I]f we were to raise prices on GRAIL, we would lose a lot more in sequencing business from the other markets. . . . The rest of our customers, whether they are in cancer detection or cancer at all, would look at what we did here and would be concerned about us doing that in the other markets that they're in. And so there would be a knock-on effect where we would lose sequencing business across our 7000 other customers who would be concerned about that kind of behavior. And so we wouldn't do that because, again, the much bigger part of our business is the sequencer business. So losses there really are much more impactful."

(PFF ¶ 877.1.) Complaint Counsel's foreclosure theory does not take these real-world constraints into account.

* * *

In short, engaging in a foreclosure strategy would cause serious damage to Illumina's NGS business and the reputation it has developed through years of investment in lowering sequencing costs while providing innovative sequencing products to any developer

willing to invest in Illumina's platform. It is implausible that Illumina would invite such harms upon itself for the speculative hope of some distant future diversion to Galleri. By ignoring such constraints, and the detrimental impact a foreclosure strategy would have on Illumina's core and by far most profitable business, Complaint Counsel presents a distorted and invalid picture of Illumina's post-merger ability and incentives to foreclose competition in the alleged MCED market. For this reason alone, Complaint Counsel cannot sustain its burden of proving that the Transaction will substantially lessen competition.

D. Complaint Counsel Disregards that NGS Costs Will be a Very Small Part of MCED Test Revenues Going Forward.

Complaint Counsel's case also falls short because it cannot be squared with the undisputed evidence that NGS costs are today a small part, and within the next few years will be a very small part, of MCED test revenues and margins. It is well established that there is "a very close relationship" between the costs of a vertically integrated firm's upstream inputs and the firm's incentive and ability to foreclose, because "that ability is going to depend on the importance of cost in the downstream firm's reliance on" the upstream firm. When input costs are a small share of downstream revenues, it shows that "there are real constraints on the ability to" foreclose downstream firms. (PFF ¶¶ 880–883.)

The evidence showed that NGS costs will be a very small part of MCED test revenues before any such test reaches commercial scale. (PFF ¶ 884.) The only evidence at trial of projected future NGS costs came from Illumina's [redacted]

[redacted][16]

Consistent with the documentary evidence from the internal business documents of Illumina [redacted], Dr. Aravanis explained that sequencing costs will continue to "decrease over time" as a percentage of Galleri's costs due to GRAIL "innovations that will lead to a decreased usage of sequencing over time," which by itself, would reduce the amount of cost associated with sequencing per test," and in addition, "Illumina is also going to lower the cost of sequencing over time," as will "other sequencing providers", which will "compound the overall reduction in sequencing costs as a fraction of the test." (PFF ¶ 902.) Mr. deSouza similarly explained that, "today sequencing costs represent about 10 percent of the price of Galleri" and "[b]y 2025, we project that sequencing costs will be less than 4 percent of the price of GRAIL's Galleri test." (PFF ¶ 903.)

[redacted]

16 [redacted]

[redacted] For example, Mr. deSouza explained that Illumina "will continue to see profit pool[s] in the sequencer business, but we believe that because of the competition in this business, the profit pools will -- the operating margin will decline over the years. And so . . . because of the competition, we expect a decline in the profit pools associated with sequencers, although it will continue to be a profitable business." (PFF ¶ 910.1.) He further noted that NGS competition is "reflected in Illumina's pricing plans and strategy" in that it "shows up in our expectation of the price of sequencing in the market, and it's continuing to decline" and "in our expectations of sort of the margin evolution in the industry". (PFF ¶ 910.2.) Similarly, Dr. Febbo explained, "[w]e have dropped the cost of sequencing through our investment in R&D, through our kind of dogged focus on making sequencing more affordable, because in research what we saw is a term we called elasticity, where the less expensive the sequencing was, the more sequencing was performed, so that it made sense to continue to drop the cost." (PFF ¶ 910.3.)

[redacted]

Where, as here, the cost of the upstream input only represents price represents only a small percentage of the downstream product price, vertical foreclosure is not a concern.[17]

E. Complaint Counsel's Theory Ignores Intensifying Upstream Competition

A necessary condition for a vertical merger to harm competition in any relevant market is a limited ability by the merged firm's rivals to switch their purchases of the related product to sufficiently close substitutes of the related product. (PFF ¶ 916.) Thus, Complaint Counsel was required to establish that Illumina has a monopoly over platforms viable for MCED development, and that there will be no viable substitutes for Illumina's NGS platforms during the relevant time period. (PFF ¶ 916.1.) Complaint Counsel failed to make that showing.

1. There Are Present and Near-Term Alternatives to Illumina.

Despite Complaint Counsel's contrary contention, there are today alternatives to Illumina as a provider of NGS products and services. (PFF ¶¶ 777–79.) As discussed above, suppliers such as Thermo Fisher, ONT and Singular are available today and can be used for MCED test development. (PFF ¶¶ 778–779.) What's more, a number of other companies are poised to offer NGS products and services in the near term. (PFF ¶¶ 782–787.) As also

[17] *See* George Raitt, THE METAPHYSICS OF MARKET POWER: THE ZERO-SUM COMPETITION AND MARKET MANIPULATION APPROACH 180 (2020) ("If the input is a relatively small part of the total costs of producing the downstream product, foreclosure would have little effect on downstream competition"); William P. Rogerson, *Modelling and Predicting the Competitive Effects of Vertical Mergers: The Bargaining Leverage over Rivals (BLR) Effect* 13, (February 28, 2020) ("[W]here the price charged by any particular upstream firm is small relative to the price of the downstream product that incorporates the input . . . even a relatively large percentage change in the price of an upstream good will result in a relatively small percentage change in the price of the downstream product, even if the entire upstream price increase is passed through to the downstream price. . . . [A] model which assumes that firms ignore these effects may still be relatively accurate even if firms do take account of these effects"); *cf. Fruehauf*, 603 F.2d at 354 (reversing Commission's order for divestiture in part because "neither the [upstream antiskid braking devices] ASBD market nor Fruehauf's [downstream] purchases in that market are likely to be significant").

described in detail above (*supra* Section I.B), there is substantial evidence that MCED test developers will have many commercially viable NGS options within the next few years, before most, if not all, MCED tests in development are ready for commercial launch. (PFF ¶¶ 782–87.) For example, BGI will enter the U.S. market not long after Illumina's patents that underlie the injunction against BGI's entry expire in 2023 and both [redacted] (PFF ¶¶ 777.3, 780.3, 780.5, 780.6.) Last year, BGI claimed that its systems can already enable a $100 genome. (PFF ¶ 594.)

Numerous Illumina executives testified about their expectations for NGS competition, including with the expiration of key patents in 2023, and how that dynamic impacts Illumina's strategies. (PFF ¶ 924.) [redacted] Ms. Berry testified that "there are numerous competitors already participating in the genomics space with instruments and consumables similar to ours", and "we anticipate that that competitive environment will . . . only become more intensive over time." (PFF ¶ 924.2.) Dr. Aravanis likewise testified that there will be "many new sequencing platforms, so a tremendous intensification of competition" and "there will be even more platforms in the coming years." (PFF ¶ 924.3.) Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would

be viable platforms for an MCED test such as Galleri. (PFF ¶ 924.4.) It is well accepted that sequencing technology is becoming substantially cheaper every year; it is thus substantially likely that all existing and future sequencing options will improve and become cheaper over time. (*See* PFF ¶ 22.)

As Dr. Carlton explained, the presence of upstream NGS alternatives on the market and in development, and the constraints they impose on Illumina, must be taken into account in analyzing Illumina's post-merger incentives and ability to substantially foreclose MCED competition. The presence of current and future NGS competitors is significant "in two ways. First, if you could substitute to another company, then that constrains what Illumina can do. . . [Second], [e]ven if you can't switch immediately, the fact that these technologies might be available . . . in the future, you really want to be focusing on not what is possible today, but you . . . really want to be talking about what are the alternatives in the future when the MCED market, to . . . when the MCED industry develops more fully." (PFF ¶ 917.) Complaint Counsel's failure to properly account for upstream competition available today and within the next few years is thus a fatal flaw in its *prima facie* case.

2. Complaint Counsel's Foreclosure Theory Is Belied by Both Investment Activity and the Purchase Price Paid by Illumina.

Investment has poured into cancer test development since Illumina announced its intention to acquire GRAIL. The timing and amount of investment activity in cancer test development is contrary to Complaint Counsel's speculation that the merger will disincentivize investment in NGS cancer screening. That surge of investment provides another basis to reject Complaint Counsel's speculative and unfounded claims of innovation harm.

Shortly after the merger was announced, analysts predicted that the deal would accelerate investment and innovation in MCED test development, 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." (PFF ¶ 928.) That is exactly what happened. For example, since Illumina announced its intent to acquire GRAIL, Exact purchased Thrive for $2.1 billion, [redacted] As Mr. deSouza observed, other liquid biopsy companies also "experienced large investment rounds after we invested, and so we saw a significant increase in investment in the MCED space after we got in, and that was very consistent with what we saw in the noninvasive prenatal testing space [another downstream testing space, discussed below, that Illumina entered through a vertical merger and that is now thriving competitively] when we entered in 2013 – investment increased there too." (PFF ¶ 930–930.1.)

The timing of this investment activity—surging immediately after Illumina announced its intent to acquire GRAIL and continuing to date—is inconsistent with Complaint Counsel's speculative theory that the Transaction will dampen incentives to invest in NGS-based cancer testing and cause innovation harms. (PFF ¶ 933.)

Further, it is undisputed that firms have been investing significant sums to develop various oncology tests on Illumina's platforms. That investment also undercuts Complaint Counsel's theory, because it shows that test developers are not, as Complaint Counsel claims, "captive" to Illumina and locked in to Illumina platforms. (PFF ¶ 933.) As Dr. Katz explained, investment in cancer test development on Illumina's platform, by itself, refutes the notion that MCED test developers are indefinitely locked into Illumina's platform or that they fear Illumina can impede their test development efforts. That is because it would be economically irrational for firms to make such large investments if they truly anticipated that they would have no options or opportunities to switch by the time their tests are commercialized and earning profits. Otherwise, these firms would be knowingly subjecting themselves to opportunistic hold-up, since (if Complaint Counsel's long-term monopoly theory had merit) Illumina would have both an incentive and ability to extract all their returns, even *without* the GRAIL merger. (PFF ¶ 938.2.)

[redacted] The substantial investment in NGS-based tests indicates that Complaint Counsel's long-term monopoly theory is unfounded.

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. (PFF ¶ 940.) Yet, she can cite no evidence to support her speculation that the market is likely to develop that way, or that the purported MCED developers she identifies have such expectations and justify their investments on this basis. (PFF ¶ 940.1.) 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." (PFF ¶ 940.2.) As Dr. Katz explained, if that were true, then the only economically logical explanation for the sunk investments she points to is that test developers—just as Illumina does—anticipate intensifying upstream competition and being able to switch to alternative platforms if Illumina attempted any opportunistic hold up. (PFF ¶ 941.) Complaint Counsel cannot carry its burden based on a theory (here, that Illumina is a long-term monopolist that can and will engage in opportunistic hold up of purported GRAIL's putative rivals) that cannot be reconciled with the real-world facts.

Similarly, the price that Illumina paid for GRAIL further undercuts Complaint Counsel's case. As Dr. Willig explained, if Complaint Counsel's theory were valid, then Illumina paying approximately $8.3 billion for the voting shares it does not already own would not make economic sense, because, even without the merger, Illumina would be able to extract most of the returns from GRAIL's commercialized sales of NGS-based cancer screening tests, including Galleri, by then increasing the prices of the essential NGS platforms that it would sell to GRAIL. (PFF ¶ 944.) Illumina's willingness to pay such a large sum for GRAIL evidences

that Illumina expects its ability to raise prices substantially in the future will be constrained. (PFF ¶ 945.) Complaint Counsel's theory of harm does not account for, and cannot explain, these real world facts.

3. Complaint Counsel's' Dismissal of NGS Competition is Unfounded.

For Complaint Counsel's theory to stand, Illumina must have a durable monopoly in the sequencing market to enable it to foreclose competition in the alleged market for MCED tests as the alleged market develops over the next several years. But in fact, the sequencing space is highly dynamic and characterized by robust competition in the near term and long term. Thermo Fisher, Oxford Nanopore, Singular and BGI already offer competing NGS technology suitable for MCED applications, and multiple new entrants such as Ultima, PacBio/Omniome, Roche and Element are specifically targeting MCED applications and customers and are poised to enter in the near future. In other words, there is no shortage of well-funded competitors currently competing for Illumina's sequencing customers—and the rush to capitalize on oncology applications has brought even greater investment and new entrants into the sequencing space. Complaint Counsel urges the Court to disregard the evidence of NGS alternatives to Illumina, but none of its arguments survives scrutiny.

First, Complaint Counsel argues that it need not account for *future* NGS competition as part of its prima facie case because, it contends, it is *Respondents*' burden to prove, likely and sufficient entry in the upstream market. That is not the law. Complaint Counsel cited to a number of horizontal merger cases for this proposition but misunderstands the context of those 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." *AT&T I*, 310 F. Supp. 3d at 192. That presumption can then be defeated by the merging parties by showing that there is likely entry that prevents the presumption of harm based on the structural features of the horizontal market at issue.

In vertical cases, no such presumption exists, and, therefore, the "timely, likely and sufficient" framework that Complaint Counsel seeks to import here does not apply. Instead, "[w]ith no presumption of harm in play, the Government . . . must make a 'fact-specific' showing that the effect of the proposed merger 'is likely to be anticompetitive.'" *Id.* Such a showing requires proving that competition will not prevent the combined firm from having an incentive and ability to foreclose rivals. As Complaint Counsel acknowledges, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" (CC Pretrial Br. at 27 (citing *United States v. Aetna, Inc.,* 240 F. Supp. 3d 1, 79 (D.D.C. 2017) (internal citation omitted)). Thus, it was Complaint Counsel's burden to demonstrate that Illumina has the ability and incentive to foreclose during the relevant timeframe—when any MCED test in development emerges as a likely rival to GRAIL, which is, at best, far in the future—and it failed to meet that burden, including because its theory cannot account for the surge of NGS investment and impending entry. Further, even if the timely, likely and sufficient framework applied, the evidence makes clear that there will be many new options available to MCED test developers, on top of the alternatives available to them today, as discussed above.

Second, Complaint Counsel contends that, 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 offered no empirical support for this assertion, despite having the burden to do so, and it did no analysis of

the size of one-time switching costs relative to the benefits of switching in a hypothetical scenario where Illumina has attempted to foreclose an MCED rival. As Dr. Carlton explained, given the magnitude of the potential downstream market—which, if it reaches its full potential, could be in the tens of billions of dollars—it cannot be assumed that even high switching costs would deter test developers from migrating to a rival platform in response to a hypothetical foreclosure strategy, since whether switching costs impede customer defections depends on not only the magnitude of switching costs but also the benefits from switching. (PFF ¶ 947.1.)

[redacted] Neither Complaint Counsel nor its expert offered any empirical assessment of the *incremental* cost of switching from an Illumina platform to a third-party platform as compared to the switching cost that would be incurred by a test developer that seeks to upgrade to Illumina's next generation system. (PFF ¶ 948.2.) On the contrary, numerous fact witnesses, as well as Dr. Cote, the only technical expert to opine on the matter, testified as to the feasibility of switching, and some Illumina customers have switched between Illumina platforms for their oncology tests. (PFF ¶ 949.)

Third, Complaint Counsel argues that 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. However, as described above, there are hundreds of millions of dollars being invested to fund these NGS entrants, many of which are specifically

targeting the screening (and other oncology) segments and have disclosed roadmaps that project commercial launch within the next few years—and in the case of Singular, late last year. (PFF ¶¶ 782–787, 923.) A number of these new entrants are led by former Illumina executives, who are extremely knowledgeable about the industry and what it takes to succeed. (PFF ¶¶ 782–787.) In speculating that all of these well-funded, serious players will simply fail, Complaint Counsel adopts an entirely inconsistent position on the evidence. With regard to the alleged MCED market, Complaint Counsel infers from the mere fact of "excitement" and "investment" in downstream test development that it is "highly likely that there are going to be several successful cancer tests" in the alleged MCED market. (PFF ¶ 926.) Yet in the upstream segment, the far more concrete evidence of innovation and investment in rival NGS platforms targeting the oncology segment (and the impending expiration of key patents) is purportedly too "uncertain" to credit. As Dr. Carlton put it:

> "[A]ll I can do is point out the asymmetry in [Complaint Counsel's expert's] analysis. None of the MCED products that [Dr. Scott Morton is] talking about exist. . . . All of them are in the future and some, as I read the evidence, far in the future. In contrast, when 'she's evaluating NGS alternatives to Illumina, even though those seem from the evidence to be more readily available and likely, she dismisses them. So I agree it's hard to make predictions, very hard, as to who will be an actual competitor in the future. That's true both for MCED and NGS, and she takes a very asymmetric stance in which she assumes that the MCED products are going to come into existence, but the NGS alternatives to Illumina are not."

(PFF ¶¶ 926.1.) Complaint Counsel cannot use a double standard to ignore the substantial evidence of alternatives to Illumina.

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

Finally, Complaint Counsel points to Illumina's prior vertical integrations into non-invasive prenatal testing ("NIPT") and Therapy Selection, its formation and spin-off of GRAIL and its formation of Helix as support for its claim that the Transaction gives Illumina the

ability and incentive to harm GRAIL's putative rivals. None of these prior instances of vertical integration support Complaint Counsel's speculative theory of harm here. Quite the opposite.

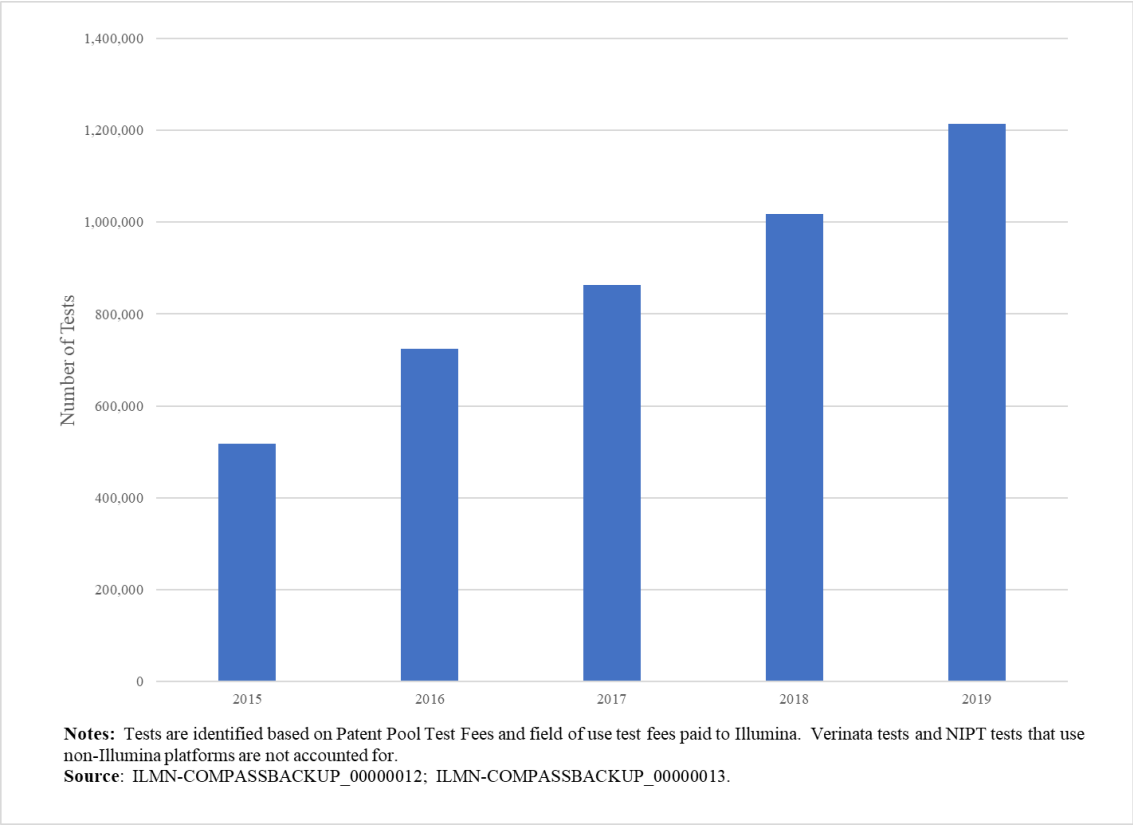
1. NIPT

Illumina's acquisition of Verinata demonstrates the flaws in Complaint Counsel's challenge to the Transaction. Rather 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. (PFF ¶ 951.) 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. (PFF ¶ 952.) 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. (PFF ¶ 953.) As in this case, Illumina was the upstream supplier of sequencing inputs to each of these companies. (PFF ¶ 954.) If Complaint Counsel's theory were correct, then one would expect to see evidence of diminished competition following Illumina's entry. (PFF ¶ 955.) The evidence is to the contrary. (PFF ¶ 955.)

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. (PFF ¶ 956.) Figure 7 below shows that total NIPT tests conducted by Verinata's rivals on Illumina's sequencing platform have more than doubled between 2015 and 2019. (PFF ¶ 956.1, Figure 7.)

Figure 7: NIPT Tests Conducted in the U.S. by Verinata Rivals on Illumina's NGS Platform



Notes: Tests are identified based on Patent Pool Test Fees and field of use test fees paid to Illumina. Verinata tests and NIPT tests that use non-Illumina platforms are not accounted for.
Source: ILMN-COMPASSBACKUP_00000012; ILMN-COMPASSBACKUP_00000013.

(PFF ¶ 956.1, Figure 7.)

In addition to the fact that total output has expanded, Verinata's share of U.S. NIPT sales has decreased. (PFF ¶ 957.) Natera, in contrast, became the market leader after Illumina acquired Verinata, with a consistently high share. (PFF ¶ 958.) Figure 8 below shows the respective shares of U.S. NIPT providers who use the Illumina NGS platform. (PFF ¶ 959.)

Figure 8: Shares of NIPT Tests Conducted in the U.S. on Illumina's NGS Platform

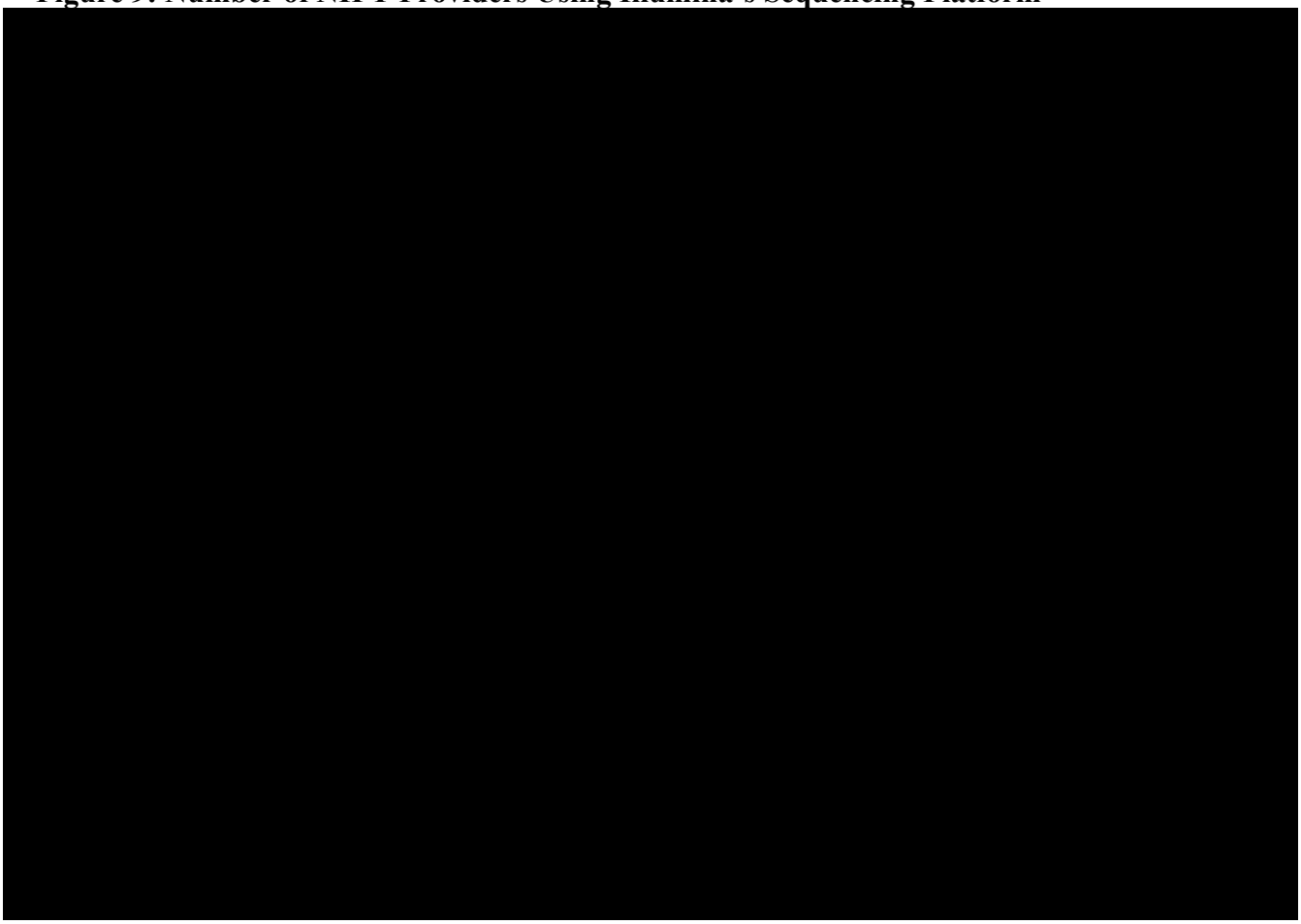
(PFF ¶ 959, Figure 8.)

If Illumina had engaged in foreclosure following the Verinata acquisition, one would expect to see Verinata's share increase after the acquisition, but instead "Verinata's share is going down" whereas Natera "has remained the number one firm in that industry", which is "just not consistent with a raising rivals' cost strategy on its face." (PFF ¶ 961.)

Furthermore, there has been a steady stream of new entry and substantial investment into NIPT testing in the U.S. since the Verinata acquisition, suggesting that downstream competitors to Verinata are not concerned that Illumina will act anticompetitively, and that Illumina has not in fact acted anticompetitively. (PFF ¶ 962.) Figure 3 below shows the NIPT providers in the U.S. that use Illumina's platform and which providers entered or exited

each year (other providers, using other sequencing platforms, may exist). (PFF ¶ 962.1.) 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). (PFF ¶ 962.2.) Overall, the number of NIPT providers on Illumina's platform has more than doubled. (PFF ¶ 962.3.) Such entry (and the significant investment required to pull it off) is inconsistent with the claim that Illumina has disadvantaged downstream rivals, or that the fear that it would do so has impeded innovation in the NIPT space. (PFF ¶ 962.3, Figure 9.)

Figure 9: Number of NIPT Providers Using Illumina's Sequencing Platform



(PFF ¶ 962.1, Figure 9.)

A number of fact witnesses confirmed what the economic evidence alone starkly demonstrates: that Illumina's entry into NIPT via a vertical transaction was decidedly procompetitive. (PFF ¶ 963.) Dr. Aravanis testified that since the Verinata acquisition, "the cost of noninvasive prenatal testing has decreased by over 90 percent"; "[t]he number of tests performed has gone up by a factor of a hundred"; "[t]he number of companies offering noninvasive prenatal tests has . . . increased significantly"; and "[t]he coverage of patients for noninvasive prenatal testing has increased by at least 100 million women." (PFF ¶ 963.1.) Similarly, Mr. deSouza testified that in NIPT, Illumina makes "eight times as much revenue selling sequencers and consumables to companies that compete with our test than we do from our own test", which is one of multiple factors driving Illumina's incentives to support all NIPT customers, including its downstream rivals, as the economic evidence demonstrates Illumina has done. (PFF ¶ 963.2.) Third parties have also attested to Illumina's positive influence in the NIPT space. For example, Invitae, an Illumina NIPT (and oncology) customer, has attested through a sworn declaration from its CEO that Illumina has been a "partner[]" and a "leader[]" in achieving payor coverage for NIPT tests for a broader set of patients, which has benefitted all market participants in that space. (PFF ¶ 963.4.) Thus, the most analogous precedent from Illumina's history squarely contradicts Complaint Counsel's baseless theory of harm.

2. Therapy Selection

Complaint Counsel cites Illumina's organic entry into therapy selection as an example of Illumina purportedly engaging in foreclosure in an area where it is vertically integrated. However, Complaint Counsel did not actually examine the therapy selection market or the impact of Illumina's vertical integration in it; and it did not examine whether there has been actual foreclosure in therapy selection or a loss of consumer welfare due to Illumina having its own therapy selection test. Complaint Counsel's "analysis" of therapy selection was based

solely on mischaracterized anecdotal evidence. In reality, the parade of horribles and innovation harms 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, which is flourishing with investment and innovation, directly contrary to Complaint Counsel's mischaracterizations.

Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors to Illumina are developing in-vitro diagnostic ("IVD") tests that will compete with Illumina's own TSO500 therapy selection test. (PFF ¶ 966.) Illumina provides customer support to its therapy selection rivals and there is increasing investment and innovation in this space in recent years. (PFF ¶ 967.) From a strategic perspective, Illumina views more test developers using its IVD platform (which it refers to as "IVD partners") as a positive regardless of whether those partners compete with Illumina's TSO500 test. (PFF ¶ 968.) As Mr. deSouza testified, "[e]ven in markets where we have our own test, so noninvasive prenatal testing, for example, or cancer therapy selection, . . . or genetic disease diagnosis – even in those markets, we make significantly more money by selling sequencers and consumables to companies that compete with our test than we do from our own test." (PFF ¶ 968.1.) He went on to explain that "[i]n cancer therapy selection, we make 14 times as much money selling sequencers and consumables to companies that compete with our test than we do from our own test", and that dynamic drives Illumina's strategy which "has been consistently to open up a market and then enable lots of players to serve that market, each with their own different approach, because we believe that maximizes the opportunity in the market." (PFF ¶ 968.2.)

Contrary to the record evidence, Complaint Counsel claims that, in the therapy selection space, Illumina has [redacted]

[redacted]

[18] 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. (PFF ¶ 964.1.)

[redacted]

[redacted][19]

[redacted]

[19] [redacted]

[redacted]

Despite the evidence to the contrary, Dr. Scott Morton concluded that the events in the therapy selection space show that Illumina has engaged in foreclosure where it is vertically integrated. (PFF ¶ 972.) Yet, Dr. Scott Morton's analysis of the therapy selection is strikingly superficial and has no probative value. As Dr. Carlton explained, if one were to do an actual economic analysis of the impact of Illumina's vertical integration into therapy selection, "the relevant question" would have to be "what's the but-for world", meaning, "was there a benefit from Illumina being vertically integrated into therapy selection and selling to Roche compared to not having Illumina in therapy selection"; and that is not what Dr. Scott Morton did by a long shot—"she pays no attention to the benefit of vertical integration of Illumina into therapy selection." (PFF ¶ 972.1–972.2.) [redacted]

[redacted] In other words, she did not do the analysis required to confirm allegations that Illumina engaged in foreclosure. The evidence Dr. Scott Morton did not examine shows that Illumina supported downstream competitors, rather than foreclosed them—directly contrary to Dr. Scott Morton's conclusions and Complaint Counsel's allegations. And, as is discussed further in Section III *infra*, the Open Offer extends this commitment to downstream customers by enabling them to develop IVD test kits for use on Illumina's platforms. (PFF ¶ 1027.)

As Dr. Joydeep Goswami, who oversees Illumina's IVD agreements, testified, "test developers are investing in developing IVD kits under the terms of [Illumina's] IVD agreements", and far from diminishing innovation in kitted oncology tests, Illumina's IVD program "spurs innovation" because test developers can "just tap into a network of instruments that is available globally that can run the assay that they're providing, so it's a huge saving of investment on their side and time on their side and resources on their side." (PFF ¶ 967.1.)

[redacted]

[redacted]

Finally, Complaint Counsel's attempt to label Illumina's IVD relationships as "foreclosure" ignores, and cannot be reconciled with, the fact that, in licensing IVD rights in a field of use and charging fees for those rights, Illumina is following market practice in the industry. [redacted] Thus, by charging fees for IVD rights in specific field of uses, Illumina is following market practice of other NGS suppliers.

In short, Illumina's conduct in therapy selection refutes Complaint Counsel's and Dr. Scott Morton's speculative claims of future harm in the alleged MCED market.

3. Population Genomics and Helix

Several of the exhibits offered by Complaint Counsel relate to Illumina's spinout of Helix, a population genomics company that competes with providers such as Ancestry.com. (PFF ¶ 974.) Notably, despite offering these exhibits and inquiring about Helix at length in depositions, Complaint Counsel did not mention the Helix spinout even once in their pre-trial brief, and for good reason: Illumina's conduct in connection with the formation and spinout of Helix was recognized, even by Helix's competitors, as "fantastic". (PFF ¶ 975.)

Complaint Counsel's witness Kenneth Chahine of Helio was formerly the executive vice president and general manager of Ancestry.com, a prominent competitor to Helix and user of Illumina's sequencing technology. (PFF ¶ 976.) Chahine testified that [redacted]

The Helix formation, like Illumina's vertical integration in NIPT and therapy selection, shows how Illumina *actually* acts when it is vertically integrated—it works procompetitively with downstream competitors, and is a "fantastic" and "phenomenal partner" to its customers. It does not restrict sequencing inputs or refuse to negotiate—nor could it, because there are current and future competitors in the NGS space to which Illumina could lose customers, and Illumina's overriding goal is to expand the usage of NGS, for which it needs its customers to be successful and willing to invest in new applications without fear of opportunistic hold-up by Illumina. [redacted]

In a case built entirely on Complaint Counsel's speculation about what Illumina might do in the future following the GRAIL merger, it is useful to consider what Illumina *has done* in analogous situations. History has shown Complaint Counsel's speculation to be baseless and inconsistent with Illumina's past behavior in other situations where Illumina has vertically integrated into downstream applications.

4. GRAIL Formation and Spinout

Finally, Complaint Counsel points to Illumina's prior relationship with GRAIL (when it previously controlled GRAIL) as an example of Illumina purportedly acting on incentives to foreclose GRAIL rivals. Specifically, Complaint Counsel points to special pricing and other benefits Illumina purportedly provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina.

These examples, however, are irrelevant to evaluating the effects of the Transaction on competition. At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep

discounting, it would be impossible for GRAIL to develop a cancer screening test. (PFF ¶ 980.) As Dr. Aravanis, who helped form GRAIL, testified, the industry reaction to the formation of GRAIL was "very, very skeptical" because the conventional wisdom was that, while GRAIL's mission was "noble", "it will be very hard, may not work at a scientific level and, even if it did, will take a very long time and be very challenging from a cost and clinical development" perspective. (PFF ¶ 980.1.) As Illumina's contemporaneous internal documents noted, at the time, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the segment, Illumina "felt an imperative to organize an entity" focused on that moon-shot mission. (PFF ¶ 980.2.) In other words, there was no one else pursuing the goal that Illumina set GRAIL on a path to pursue. (PFF ¶ 980.3.) Any special pricing at that time was not designed to put rivals at a disadvantage. (PFF ¶ 980.3.) There were no rivals. (PFF ¶ 980.3.) The goal was in fact to *accelerate* the development of the cancer screening space by years, which would benefit others who might seek to invest in the space. (PFF ¶ 980.3.)

These considerations from the time of GRAIL's formation no longer exist for many reasons, including because (i) the cost of sequencing has come down since 2016; and (ii) Illumina's assumptions about the volume of sequencing required to develop a cancer screening test were significantly higher than what is actually required as the technology was developed. (PFF ¶ 981.) In any event, GRAIL's test is now already available. (PFF ¶ 1128.1.) As discussed below, Illumina has committed through its Open Offer to provide the same pricing terms to all oncology test developers. Complaint Counsel fails to explain how these facts are consistent with its theory.

* * *

Thus, on top of its failure to prove either its alleged relevant market or its alleged related market allegations, Complaint Counsel's case lacks merit because it relies on baseless speculation and fails to contend with the evidence in the record. Its proof falls woefully short of what is required to meet its burden in challenging this purely vertical merger. With no presumptions of competitive harm available to it, and with no elimination of any upstream or downstream competitor caused by the Transaction, Complaint Counsel had to meet its burden with facts showing that the Transaction is one of the rare vertical mergers that is *likely* to harm competition. Complaint Counsel did not come close to satisfying this burden. Critically, Complaint Counsel's speculation fails to substantiate its prediction of material diversion to Galleri from the alleged foreclosure strategy and fails to account for the effects of such a strategy on Illumina's NGS business and reputation. It also fails to account for competition today and in the future that would make any foreclosure strategy impractical and ineffective. Finally, evidence from Illumina's past vertical integrations proves that, contrary to Complaint Counsel's claims, the Transaction will benefit patients and consumers.

III. COMPLAINT COUNSEL ERRS IN DISMISSING THE OPEN OFFER.

Assuming, *arguendo*, that the Transaction would give Illumina an incentive and ability to foreclose GRAIL's putative rivals in the absence of any contractual commitments not to do so, the Open Offer prevents any possible anticompetitive harms. The Open Offer provides comprehensive, long-term protections for customers regarding every "lever" that Complaint Counsel argues Illumina could pull to disadvantage potential GRAIL rivals. It ensures that Illumina remains incentivized to support customers' development of MCED tests. And it accounts for any possible anticompetitive effects while still allowing for the life-saving benefits of the Transaction, which would not be achieved by Complaint Counsel's remedy of divestiture. Thus, not only does Complaint Counsel fail to properly account for the real-world fact of the

Open Offer when balancing the Transaction's alleged anticompetitive harm against the resulting efficiencies, *see supra* Section II, but it also errs in dismissing the Open Offer as a viable solution to any alleged anticompetitive harms.

A. The Open Offer Was Developed in Consultation with Illumina Customers and is Designed to Allay Any Concerns by Either The FTC or Any Customer Arising from the Transaction.

Since announcing the Transaction, Illumina has remained committed to ensuring that its customers, including potential GRAIL rivals, are secure in their relationship with Illumina post-merger. This process began through telephone outreach to individual customers to answer their questions about the Transaction and assure them that their relationship with Illumina would remain unchanged. [redacted] In early October 2020, Illumina's commercial team followed up its telephone outreach with letters of intent (LOIs) to formalize and document specific assurances provided to customers over the phone. [redacted] These LOIs were amended later in October 2020, to provide additional protections to customers. [redacted] The LOIs provided assurances that, after the Transaction, customers would be able to purchase Illumina's products on terms and conditions similar to those available to them prior to the Transaction; that customers would receive commercial terms comparable to those provided to other, similarly situated, customers; that Illumina would ensure availability of its platforms and support services; and that customers' confidential information would be protected. [redacted]

During this outreach, Illumina engaged in extended negotiations with several customers, including [redacted] for long-term supply agreements. [redacted] These negotiations taught Illumina more about customers' concerns regarding the Transaction, and showed Illumina how those concerns could be fully resolved. To address concerns raised by customers, Illumina developed exhaustive supply agreements with protections

for, *inter alia*, access to products and services, equitable pricing, and confidentiality. [redacted] [redacted] These agreements were satisfactory to customers [redacted] and sufficient to resolve customer concerns with the Transaction. [redacted] Based on what Illumina learned during its customer outreach and individual supply agreement negotiations, Illumina developed a standardized supply contract (the Open Offer) to extend to all of its United States oncology customers. (PFF ¶ 990.) Illumina made the Open Offer available on its website on March 30, 2021. (PFF ¶ 991.)

The Open Offer announces its purpose in the publicly available version posted on Illumina's website: "to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction". (PFF ¶¶ 998.2, 1056.1.) The Open Offer achieves this purpose by setting forth a binding offer between Illumina and any Open Offer signatory that lasts twelve years—a term length that is both long enough to address the alleged anticompetitive harms and consistent with the term lengths of consent decrees previously approved by the FTC and DOJ. (PFF ¶¶ 1000–1000.3); *Broadcom Inc.*, FTC Docket No. C-4622, at 11 (Aug. 17, 2017) (consent order) (ten years); *Sycamore Partners II*, FTC Docket No. C-4667, at 19 (Jan. 25, 2019) (consent order) (ten years).

During the twelve-year term, customers who sign the Open Offer will benefit from all-encompassing protections that prevent any foreclosure by Illumina, including (among others):

- Access to Illumina's product and support services that is equivalent to that provided to GRAIL or any other For-Profit Entity (PFF ¶ 1004);[20]

[20] Under the Open Offer, a For-Profit Entity is defined as "a for-profit company in the United States that purchases Supplied Products for performing sequencing for liquid biopsy cancer screening or diagnostic tests for clinical oncology purposes, on human samples received from, and delivered to, unaffiliated health care professionals, health care organizations or other

- Access to Illumina's current and future sequencing products (as well as information about final product specifications) that is equivalent to that provided to GRAIL or any other For-Profit Entity (PFF ¶¶ 1005, 1007);

- Continued supply of all sequencing products purchased by the customer and equitable allocation of supply during any supply shortage (PFF ¶ 1012);

- Access to the pricing that the customer received before the GRAIL transaction ("Grandfathered Pricing") and to most-favored-nation ("MFN") pricing protections under a standardized, volume-based pricing grid (PFF ¶¶ 1014, 1017);

- The guarantee that sequencing prices will not increase beyond inflation over the full twelve-year term and that prices will decrease by at least 43% by 2025 (PFF ¶¶ 1021, 1023);

- Rights, under Illumina's core intellectual property, to use the products purchased under the Open Offer (PFF ¶ 1036);

- The opportunity to enter into, at any time within the six years after the close of the Transaction, separate agreements with Illumina to develop IVD test kits on Illumina's FDA-regulated instruments and to work with Illumina to modify Illumina's products to optimize interoperability with the customer's tests (PFF ¶ 1010, 1026);

- Protection from the improper use of customers' competitively sensitive information (PFF ¶¶ 1038, 1039, 1040);

- The unilateral right of the customer to terminate the supply agreement at any time and for any reason (PFF ¶ 1001); and

- Robust enforcement provisions, including biannual audits of Illumina's compliance and binding arbitration in the event of any dispute. (PFF ¶ 1043.)

The protections of the Open Offer are comprehensive. They provide many customers benefits beyond those in the supply agreements entered into prior to the announcement of the Transaction. (PFF ¶ 999.) Complaint Counsel's own expert could not identify a single supply agreement that Illumina had previously entered into with any of its customers that had protections on pricing, access to products and services, firewalls, audits and

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laboratories for clinical oncology purposes." It "excludes governments, government agencies, hospitals, research institutes, academic institutions, nonprofits and Illumina Affiliates (including GRAIL)." (PFF ¶ 993.1.)

arbitration like those in the Open Offer. [redacted] The Open Offer even extends beyond what customers and purported MCED test developers asked of Illumina in individual negotiations. [redacted] Under the Open Offer, however, Illumina commits not to obsolesce any sequencing instruments or core consumables at all, provided that any oncology customer has purchased them in the last year. [redacted] Illumina developed customer protections that extend beyond those requested by individual customers because its primary goal was to guarantee that ***all*** of its customers, including any potential GRAIL competitors, were secure in their supply relationships with Illumina after the Transaction. (PFF ¶ 1000.2.)

The manifest benefits and robust protections of the Open Offer are reflected by customer interest. [redacted] This number will only

continue to grow as more customers realize the benefits that the Open Offer will provide. Customers can continue to sign the Open Offer at any time until six years after the close of the Transaction. (PFF ¶ 995.) As customers continue to sign the Open Offer, Illumina is already working to operationalize the Open Offer's provisions. For example, to implement the Open Offer's terms, Illumina has entered into a contract with Deloitte to help Illumina develop systems and procedures that guarantee Illumina's compliance. (PFF ¶ 1017.3.)

Thus, from the moment Illumina announced its intent to acquire GRAIL, Illumina has taken proactive steps to address any concerns from the Transaction by building an airtight framework to ensure any putative GRAIL rival (and all Illumina oncology customers) is treated equitably, and it has done so without sacrificing the merger-specific benefits of the Transaction.

B. The Open Offer Addresses Each of the Foreclosure Concerns Raised by Complaint Counsel and by Certain Customers.

Complaint Counsel's dismissal of the Open Offer is misguided. Courts adjudicating merger challenges frequently find proposed remedies like the Open Offer sufficient to address the alleged anticompetitive harms. *See, e.g., United States v. AT&T, Inc.* (*AT&T II*), 916 F.3d 1029, 1042–43 (D.C. Cir. 2019) (holding, in a vertical merger case, that "Turner Broadcasting's irrevocable offers of no-blackout arbitration agreements" made the merger "unlikely to afford Turner Broadcasting increased bargaining leverage", the government's primary theory of harm); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1298 (W.D. Mich. 1996) (holding that merging hospitals had successfully rebutted FTC's *prima facie* case and evidence in light of the hospitals' proposed "Community Commitment", which served as an "additional assurance that the merged entity would not exercise its market power to raise prices or otherwise injure the community"); *see also FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 304 (D.D.C. 2020) (holding that "any anticompetitive effects of the merger in the proposed Pacific

Northwest geographic market are resolved by PeroxyChem's proposed divestiture of its Prince George plant"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 223, 225, 233 (S.D.N.Y. 2020) (holding that Defendants successfully rebutted Plaintiff States' *prima facie* case because the proposed remedies and conditions to the transaction "significantly reduce the concerns and persuasive force of Plaintiff States' market share statistics"); *FTC v. Atlantic Richfield Co.*, 549 F.2d 289, 299 (4th Cir. 1977) (holding that the FTC's claim that the merger would substantially lessen competition was rendered "moot" by subsequent post-merger agreement to divest certain assets).

The Open Offer accomplishes precisely that here. Although Complaint Counsel has failed to make out a *prima facie* case for the reasons explained above, the Open Offer addresses, point-by-point, each of the foreclosure concerns raised by Complaint Counsel and customers. Complaint Counsel and certain customers have asserted that Illumina could disadvantage potential GRAIL rivals by withholding access to services or products, manipulating prices, refusing to provide support for regulatory approval of customer tests, asserting intellectual property rights to prevent customer access to NGS products, or misusing customers' confidential information. They have also argued that whatever the Open Offer does to address these concerns is irrelevant because the Open Offer is unenforceable. Complaint Counsel and these customers are wrong on every account. (PFF ¶¶ 997–997.4.)

Access to Services. Complaint Counsel has alleged, and certain customers have contended, that Illumina can disadvantage GRAIL's putative rivals after the Transaction by delaying or disrupting support services. However, the Open Offer prevents Illumina from attempting such tactics by expressly requiring that Illumina provide a customer access to "the same product services and support services" to which GRAIL or any For-Profit Entity has

access, or to which the customer had access before the Transaction, and at the same prices. (PFF ¶¶ 1004–1004.1.)

Pursuant to this access-to-services provision, Illumina cannot delay technical support in a way that would affect customers' development of screening tests because delaying support or refusing to service an instrument would amount to a breach. (PFF ¶ 1004.7.) If Illumina attempted to provide worse services to an oncology customer, including a hypothetical GRAIL rival, that would constitute a breach of the Open Offer. (PFF ¶ 1004.7.) Illumina similarly cannot avoid its obligations under the access to services provision by deliberately sending an inexperienced technician to service a GRAIL rival's instrument because a service is only considered delivered when the service case is closed. (PFF ¶¶ 1004.5–1004.6.) As noted above, Illumina has no incentive to delay service or to provide worse services to customers or purported GRAIL competitors because doing so would hurt Illumina's overall business: As Illumina's Senior Vice President and General Manager of the Americas Commercial Team, Nicole Berry, testified, "[W]hen instruments are down, customers aren't buying kits from [Illumina]," so there is every incentive for Illumina to provide support services that are prompt and effective for every customer. (PFF ¶ 1004.7.) But, in any case, the Open Offer requires Illumina to do so.

Complaint Counsel has suggested that the access-to-services provision cannot be implemented effectively because "services" are undefined in the Open Offer and because there is no way for a customer (or auditor or arbitrator) to evaluate the level of service that a given customer receives compared to that received by GRAIL. But courts have found that similar service provisions help resolve antitrust concerns. *See, e.g.*, *Butterworth*, 946 F. Supp. at 1306–07 (approving a proposed five-part consent order, one part of which consisted of a promise to

continue providing services to medically needy people). More importantly, this suggestion by Complaint Counsel misunderstands the product and support services offered by Illumina, as well as the efforts taken to carefully track the level of service provided. Customers purchase service contracts from a standardized list of service SKUs, just like the standardized list of purchasable product SKUs. (PFF ¶ 1004.4.) These contracts may be purchased at one of three standardized service levels, which offer different levels of service, including frequency of service, for different prices. (PFF ¶ 1004.3.) Thus, what counts as a service can be easily defined and tracked.

Moreover, to ensure consistency of service at each level, Illumina tracks individual cases using key performance indicators ("KPIs") such as total instrument downtime and length of time between when a service case is opened and when it is closed. (PFF ¶ 1004.6.) This tracking enables Illumina to guarantee consistent treatment across customers. (PFF ¶ 1004.6.) Illumina's service and support efforts and KPIs are well documented in Illumina's systems and known to customers who have ample experience with Illumina's pre-merger service levels. There is simply no basis to conclude that an auditor or arbitrator cannot figure out if Illumina is in fact providing degraded services to a GRAIL rival given the wealth of detailed information available on Illumina's normal course service and support levels. [redacted]

Accordingly, the Open Offer's access-to-services provision can be effectively implemented, monitored and enforced, and it fully addresses any concern that Illumina could foreclose purported GRAIL rivals by providing lower quality service.

Access to Products. Complaint Counsel and certain customers have also suggested that Illumina could disadvantage purported GRAIL rivals by withholding access to Illumina's products, including future products, but, here too, the Open Offer provides a complete solution. (PFF ¶ 1005.) The Open Offer requires that customers have access to the same sequencing instruments and core consumables that GRAIL or any For-Profit Entity has access to within five days of when GRAIL or such For-Profit Entity receives access. (PFF ¶¶ 1005–1005.1.) Similarly, Illumina must provide customers with the same information about final product specifications of any sequencing instruments or core consumables within five days of providing such information to GRAIL. (PFF ¶ 1006.) Finally, to the extent that GRAIL or any other For-Profit Entity receives access to any sequencing instruments or core consumables that are not yet available for purchase in Illumina's product catalogue (*i.e.*, "Pre-Release" sequencing products), Illumina must also make such products available to other Open Offer customers within five days. (PFF ¶¶ 1008–1008.2.) [redacted]

Given these extensive access provisions, Illumina cannot withhold access to products in a way that materially disadvantages any potential GRAIL rival. Together, these provisions guarantee that if Illumina makes any material improvement to an NGS instrument or core consumable, it cannot limit these improvements to GRAIL or any other particular customer. (PFF ¶ 1007.2.) Similarly, under these terms, Illumina cannot design a new product or new version of an NGS instrument or core consumable product specifically for GRAIL or any other

customer without making that product available to everyone. (PFF ¶¶ 1005, 1005.2, 1007, 1007.2.) And any of these new products, versions or improvements must be made available to customers within a mere *five days* from when they are made available to GRAIL. (PFF ¶¶ 1005.1, 1007.1.) Considering the length of time required to develop a test, five days is plainly an "inconsequential amount of time" that could confer no advantage on GRAIL vis-à-vis other test developers. (PFF ¶¶ 1008.6.) When Illumina releases a new product, customers tend to wait for a year or more before adopting the product. (PFF ¶ 1090.1.) For example, Illumina's NovaSeq instrument was released in the first half of 2017, but a substantial portion of Illumina's customers are only now completely adopting the NovaSeq. (PFF ¶ 1090.3.) So, by ensuring customers have access to products within five days of when GRAIL or another For-Profit Entity receives access, the Open Offer fully resolves any concern about access to current or future sequencing products.

In addition to the equivalent access provisions, the Open Offer also assures customers that they will have an uninterrupted and predictable supply of all of the sequencing products that they purchase. Specifically, the Open Offer prohibits Illumina from discontinuing a product if a customer has purchased it within the last year. (PFF ¶ 1011.) This "no obsolescence" term also interacts with the pricing terms described below, *see infra* Section 1.B (Pricing), to ensure that Illumina cannot raise prices on existing products, ensuring that customers are, in the words of remedies expert Ms. Margaret Guerin-Calvert, "certainly no worse off than in the current world". (PFF ¶ 1011.8.) Contrary to the unfounded claims of one Illumina customer, Natera, Illumina also cannot "monkey" with supply by providing lower quality products or delaying purchase orders without breaching the Open Offer. (PFF ¶¶ 1092–1092.1.) In the event of a supply shortage, Illumina is required to allocate existing supply

equitably based on expiring lots, rather than favor particular customers (including GRAIL). (PFF ¶¶ 1012–1012.1.) Finally, Illumina cannot cease shipments of supply based solely on a claim that a customer has infringed Illumina's intellectual property, no matter how well-founded the claim. (PFF ¶ 1037.) In other words, the Open Offer accounts for and prevents all foreseeable circumstances in which Illumina theoretically could (but for the Open Offer) withhold, delay or disrupt supply of a given sequencing product.

In addition to these constraints, the Open Offer also affirmatively requires Illumina to enter into separate agreements, upon a customer's request, to customize Illumina's sequencing products to optimize compatibility with that customer's products. (PFF ¶¶ 1010–1010.1.) This is a completely novel commitment and benefit for customers that Illumina has not provided in the past. (PFF ¶¶ 1010.3.) In the past, customers have developed their tests, including oncology tests, without Illumina's developmental assistance or optimization support. (PFF ¶¶ 1010.4.) Illumina's customers typically purchase Illumina's products "off the shelf" and do not commission Illumina to make customized sequencing equipment. (PFF ¶¶ 1010.7.) Customers *prefer* to develop their tests on their own because they do not want to share key algorithms or analyses used to analyze the genetic data—*i.e.*, the "secret sauce"—with Illumina. (PFF ¶ 1010.7.1.) Even GRAIL, which has had a close relationship with Illumina and in which Illumina had a 12% stake pre-Transaction, refused to share information about its Galleri test with Illumina or enter into a collaboration agreement. [redacted] Thus, based on past practice, development support is not even needed for Illumina's customers to create tests to run on Illumina's platforms. Nonetheless, FMI requested a provision on development support, and Illumina added this provision to accommodate, in a customer-friendly way, all possible requests it was likely to receive over the twelve-year term. (PFF ¶¶ 1010.2, 1010.8.) Far from

disadvantaging GRAIL's putative rivals, then, the Open Offer requires Illumina to affirmatively support them in a way that it otherwise would not, and, contrary to Complaint Counsel's claims, is comprehensive enough to address potential evolutions in the way customers may seek to work with Illumina in the future. (PFF ¶ 1010.10.)

These provisions thus ensure that customers receive access to the same products that GRAIL and other For-Profit Entities have access to, that Illumina does not disrupt or delay supply of customers' purchased products and that Illumina will modify its products to maximize interoperability with customers' tests. As a result, the Open Offer addresses any possibility that Illumina could foreclose potential GRAIL rivals by restricting their access to Illumina's products, and it even includes additional benefits that customers would not have access to absent the Transaction.

Pricing. Contrary to the suggestions of Complaint Counsel and certain customers, Illumina cannot foreclose GRAIL's putative rivals by raising their prices relative to what they would have received absent the Transaction. First, for each product that they purchase under the Open Offer, customers may choose either grandfathered pricing based on the prices available to them before the Transaction closed ("Grandfathered Pricing") or pricing under a universal grid ("Universal Pricing"), as discussed in greater detail below. (PFF ¶ 1014.)

If a customer chooses Universal Pricing, it will receive most-favored nation ("MFN") pricing protections relative to both GRAIL and to any other For-Profit Entity. (PFF ¶¶ 1017, 1018.) Further, the Universal Pricing is based on the pricing Illumina projected for GRAIL in its deal model and is more favorable than pricing Illumina charged many of its oncology customers before the Transaction. These provisions ensure that no customer receives less favorable pricing than they would have absent the Transaction, which directly addresses any

concern that Illumina would attempt to raise rivals' costs. Further, [redacted]

While Complaint Counsel has made much of the possibility that Illumina could use discretionary discounts to treat customers inequitably, the Open Offer expressly addresses this and resolves Complaint Counsel's purported concerns. Under the MFN provisions, any discretionary discounts offered to GRAIL or any other For-Profit Entity must be made available to all other Open Offer customers. (PFF ¶ 1017.4) To the extent Illumina offers more favorable pricing to GRAIL or any For-Profit Entity, it must promptly notify other Open Offer customers, make the more favorable pricing available to them and refund any difference between the price paid by an Open Offer customer and the applicable reduced price. (PFF ¶ 1019.) Thus, the Open Offer ensures that customers receive fair pricing, which not only prevents disadvantaging GRAIL's putative rivals, but also represents an improvement over the status quo, in which customers have no contractual protections against price discrimination. [redacted]

Further, to the extent that a customer prefers to retain the pricing that it had before the Transaction, the Open Offer allows the customer to do so by choosing Grandfathered Pricing for each product purchased under the Open Offer. (PFF ¶ 1015.) Because Illumina is prohibited from discontinuing products that customers continue to purchase, a customer may choose to continue purchasing the same products it did before the Transaction and at the same prices ***for***

the entire term of the Open Offer—twelve years. (PFF ¶¶ 1015.1–1015.3.) The Grandfathered Pricing provision was included in the Open Offer to give customers the benefit of flexibility and make the Open Offer as customer-friendly as possible: Even though nearly all customers will receive better pricing under the Universal Pricing option, customers may still prefer their pre-merger pricing, and so they can elect to maintain that pricing if they wish. (PFF ¶ 1015.2.) Thus, the Grandfathered Pricing provision gives choice to customers with pre-merger supply agreements or pre-merger standing quotes.

In addition to the MFN and Grandfathered Pricing provisions, the Open Offer also prohibits Illumina from raising prices beyond inflation for sequencing instruments and core consumables for the entire twelve-year term. (PFF ¶ 1021.) If Illumina releases a new sequencing instrument or sequencing (core) consumable or a new version of an existing instrument or sequencing consumable, it ***cannot*** increase prices from the previous version unless the new product or version represents a material improvement. (PFF ¶ 1022.) Even if the new product represents a material improvement over the previous product, the price must take the value of that improvement into account and must be commercially reasonable. (PFF ¶ 1022.2.) Whether the new price is, in fact, commercially reasonable is subject to arbitration, and further, in any arbitration in which the price of a new version of a product or new product is disputed, the arbitrator is empowered to determine the reasonableness of the price, including the value of the any improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer. (PFF ¶ 1022.2.) All of these provisions work together to prevent Illumina from escaping its promise not to increase sequencing pricing over the term: By requiring that the pricing of any new product be commercially reasonable considering the value of any improvements, with the

threat of effective, baseball-style arbitration as an enforcement mechanism, Illumina cannot simply redefine what counts as a new product and increase prices as it chooses. (PFF ¶¶ 1022.2–1022.3.) Thus, the Open Offer guarantees that Illumina cannot disadvantage any GRAIL rival by increasing sequencing prices.

Finally, beyond promising not to increase prices for the twelve-year term, Illumina also commits to at least a 43% reduction in the price of sequencing by 2025. (PFF ¶ 1023.) In other words, the Open Offer does more than guarantee that customers' prices will not get worse; ***it guarantees that they will get better***. As noted, that reduction is based on what Illumina had projected for GRAIL's pricing in its deal model—in other words, Illumina is guaranteeing all oncology customers the price declines it assumed in its financial projections for the transaction upon which it based its valuation of GRAIL. (PFF ¶ 1023.6.) While Dr. Scott Morton argued that the price of sequencing could be even lower without the Transaction, her analysis on this point is deeply flawed and ignores that the 43% decline is based on Illumina's deal model, in which Illumina had every incentive to understand likely future cost reductions for determining the purchase price for the Transaction. (PFF ¶ 1023.6.) Further, it is possible that, absent the Transaction, Illumina could not reduce sequencing costs by 43% by 2025 for a variety of reasons, and Dr. Scott Morton has not established otherwise. Dr. Scott Morton's contention that prices could be lower absent the Transaction is mere speculation and contrary to Illumina's normal course projections. Dr. Scott Morton acknowledged that, without the merger, sequencing prices could decrease by *less than* 43% by 2025. [redacted] Under the Open Offer, however, Illumina is contractually committed to a 43% price reduction, so if Illumina failed to meet its goal of reducing pricing by 43%, a customer could obtain relief from Illumina's breach. (PFF ¶ 1055 (providing for binding arbitration, in which the arbitrator is empowered to award

"any relief necessary", including monetary relief).) Thus, the Open Offer's price reduction term represents a significant improvement for customers over the pre-Transaction status quo. (PFF ¶ 1023.12.)

In *Butterworth*, the court analyzed a similar provision set forth by the merging parties relating to future pricing and held it "***undermine[d] the predictive value of the FTC's prima facie case***". 946 F. Supp. at 1298 (emphasis added). There, merging hospitals offered a "Community Commitment" that reiterated the hospitals' "strong conviction that the purpose and intent of the transaction is to reduce costs—and to pass those cost savings on to consumers—rather than to increase prices or unfairly disadvantage payers." *Id.* The Community Commitment provided that "the merged entity will limit increases in charges to no more than the annual percentage increase" in the regional Consumer Price Index for seven years after the merger. *Id.* at 1298, 1305. The FTC "contend[ed that] this commitment offers inadequate assurances to the community because it is temporary and because it is illusory inasmuch as hospital price increases have been decelerating in recent years and prices may even decrease in the future." *Id.* at 1298. But the Court rejected the FTC's arguments, holding that the Community Commitment "besp[oke] a serious commitment by defendants—a commitment to which they can be held accountable—to refrain from exercising market power in ways injurious to the consuming public." *Id.* Here, too, Complaint Counsel's objections to the Open Offer should be discarded.

Thus, through the MFN protections, guaranteed legacy pricing on all products that a customer purchases for twelve years, guaranteed lack of price increases and a guaranteed price decrease of 43% that matches the decline in price that Illumina projected for GRAIL when

analyzing the transaction, the Open Offer ensures that Illumina cannot disadvantage GRAIL's putative rivals through pricing.

FDA Approval. Complaint Counsel and certain customers have suggested that Illumina could foreclose GRAIL's putative rivals by withholding information necessary for those rivals to obtain FDA approval for their tests, but this is mistaken. The Open Offer ensures that Illumina provides the necessary support to potential GRAIL rivals in two ways. *First*, the Open Offer ensures that "Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test" using Illumina's NGS products. (PFF ¶ 1027.1.) It is expected that any MCED test developer will launch its test as laboratory-developed tests ("LDTs") (as GRAIL has done) and/or pursue the single-site premarket approval ("PMA") option (as GRAIL is doing). *See supra* Section I.A.3.b. This Open Offer provision guarantees that customers have what they need from Illumina to obtain single-site PMA approval.

Second, the Open Offer allows customers to enter into agreements with Illumina under which customers can develop and commercialize IVD test kits for use on Illumina's platforms. (PFF ¶ 1027.) Illumina must provide customers with standard terms for these agreements and provide documentation to assist customers with FDA approval or marketing authorization. (PFF ¶ 1027.1.) The standardized terms for the IVD agreements include a right of reference to any relevant Illumina regulatory documentation, which allows a test developer to reference Illumina's files obtaining approval of its sequencing instruments in any regulatory submission. (PFF ¶ 1027.2.) Customers may elect to enter into these separate IVD agreements—which have terms as long as 15 years from the date the Transaction closed—at any point up to six years after the close of the Transaction. (PFF ¶¶ 1026, 1040.)

Before the Transaction and the Open Offer, Illumina had no obligation to assist customers in seeking FDA approval, except where it had already entered into an agreement with a customer that required such assistance. (PFF ¶ 1035.2.) Historically, Illumina has provided very little assistance in the regulatory approval process for its customers' products. For test developers pursuing an LDT or a single-site PMA, Illumina plays a "very minimal role", as the developer alone is responsible for the design of the test and for ongoing quality management. (PFF ¶ 1414.) Thus, Illumina's relationship to the developer is "mostly as a supplier", rather than a partner in seeking regulatory approval. (PFF ¶ 1414.) Even if a customer were to develop a kitted or distributed IVD test on Illumina's instruments, Illumina's sole responsibility from the FDA's perspective is in ensuring the quality of the Illumina products used by the developer, which is precisely what the Open Offer terms, including the IVD agreements, guarantee. (PFF ¶ 1415.) The developer retains sole responsibility for ensuring that their test meets regulatory requirements. (PFF ¶ 1415.) These Open Offer terms thus guarantee that Illumina will make available equal or greater assistance to MCED test developers with respect to FDA approval of potential MCED tests than it did before the Transaction. (PFF ¶ 1035.3.) As a result, the Open Offer prevents Illumina from foreclosing potential GRAIL rivals by withholding assistance in FDA approval of a putative rival MCED test.

Intellectual Property. Complaint Counsel and certain customers have also suggested that Illumina could 'use its intellectual property to foreclose any GRAIL rival, but this is incorrect. The Open Offer expressly provides that customers have the right to use the products purchased through the Open Offer under Illumina's core IP, which refers to the intellectual property rights covering aspects of Illumina's sequencing products that are common to all applications and all fields of use. (PFF ¶¶ 1036–1036.4.) This ensures that there will be no

confusion about whether these core IP rights will be provided to customers in the future. (PFF ¶ 1098.) Further, as explained above, *see supra* Section 1.B (Access to Products), the Open Offer prohibits Illumina from ceasing shipments of products based solely on a claim of IP infringement by a customer, no matter how well-founded the claim. (PFF ¶ 1037.) Thus, regardless of any disputes, Illumina cannot use IP litigation or threatened IP litigation as a guise for foreclosing GRAIL's putative rivals.

Confidentiality. Finally, Complaint Counsel and certain customers have suggested that Illumina could favor GRAIL by using GRAIL's putative rivals' competitively sensitive information to assist GRAIL, but under the Open Offer, this is not possible. The Open Offer requires that, to the extent Illumina has access to customers' competitively sensitive information, it may not share this information with GRAIL, any GRAIL subsidiary or any Illumina employees who work with GRAIL. (PFF ¶ 1038.) Further, Illumina must establish a firewall to prevent customer confidential information from being exchanged between Illumina and GRAIL. (PFF ¶ 1039.) These provisions work together to ensure that customers' confidential information remains safe and is not used by Illumina or GRAIL to gain a competitive advantage. [redacted]

Contrary to the suggestions of Complaint Counsel and certain customers, the Open Offer's confidentiality provisions can be effectively administered. Firewalls in general are not novel or unusual and have been implemented by the FTC (and other agencies) in vertical transactions with success. (PFF ¶ 1041.1); *see also Broadcom Inc.*, FTC Docket No. C-4622 at 5–7 (Aug. 17, 2017); *Evanston Northwestern Healthcare Corp.*, FTC Docket No. 9315 at 6 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Docket No. C-4652, at 9–13 (June 5, 2018);

PepsiCo, Inc., FTC Docket No. C-4301, at 6–9 (Sept. 27, 2010); *Sycamore Partners II*, FTC Docket No. C-4667, at 7 (Jan. 25, 2019). [redacted]

The Open Offer's firewall provision, specifically, will have the essential characteristics of an effective firewall: It will provide for monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶ 1041.5.) Illumina is familiar with how to set up effective confidentiality procedures, because it already utilizes elaborate procedures to protect the confidentiality of information it receives from its partners. (PFF ¶ 1041.3.) For example, in the process of negotiating IVD agreements with potential partners, Illumina protects customer confidentiality by creating clear confidentiality agreements early in the process, training staff extensively on confidentiality, separating teams who work with customers with similar products, utilizing document control processes and giving legal guidance in the event of a confidentiality question. (PFF ¶¶ 1040–1040.8.) This experience will assist Illumina in developing a robust firewall between itself and GRAIL, and indeed, Illumina has already drawn on this experience to implement the appropriate firewall and confidentiality provisions. (PFF ¶¶ 1041.2–1041.3.) Finally, Illumina is working with Deloitte to operationalize the terms of the Open Offer, and the efficacy of Illumina's firewall will be part of the biannual audits described below. (PFF ¶¶ 1051.3–1052); *see infra* Section 1.B (Enforcement). All of this will ensure that Illumina's firewall functions as intended and thus prevents any use of confidential information to disadvantage GRAIL's putative rivals. As a result, the Open Offer prevents Illumina from misusing customer confidential information.

Enforcement. In addition to the substantive provisions discussed above, *see supra* Section 1.B (Access to Products–Confidentiality), the Open Offer provides for extensive enforcement mechanisms to ensure that Illumina adheres to its commitments. First, the Open Offer commits Illumina to biannual audits by a third-party auditor selected from among the "Big 4" to monitor Illumina's compliance. (PFF ¶ 1047.1.) [redacted] And the Open Offer provides a way to remedy any such breaches because, if a customer has a good-faith basis for alleging that Illumina has breached the Open Offer, Illumina must engage an auditor to assess the allegation, separate from the biannual audits. (PFF ¶ 1047.2.) Finally, Illumina is required to provide customers with a written report of the audits and to ensure that customers are notified of any potential noncompliance within ten days. (PFF ¶ 1048.) Thus, the Open Offer's audit provision guarantees that customers receive sufficient notice of any possible breach by Illumina.

The audit provision of the Open Offer works in conjunction with a provision requiring binding arbitration in the event of a breach. Under this provision, in the event of a breach by Illumina, the auditor is empowered to order "any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." (PFF ¶ 1055.) The arbitrator's decision is required to reflect the fact that the purpose of the Open Offer is to allay concerns relating to the Transaction. (PFF ¶ 1056.) By providing a mechanism for resolving disputes through an independent entity in a way that aligns with the purpose of the Open Offer, the arbitration provision buttresses the audit provision to enable effective enforcement of the Open Offer. Together, these enforcement provisions help guarantee that the Open Offer "will

have real-world effects" and put Illumina's "'money where [its] mouth is' in showing that the proposed merger, far from being aimed at 'doing any of the things that the government alleges,' is instead a 'vision deal' being pursued to achieve 'lower prices, improved quality, enhanced service, and new products.'" *United States v. AT&T Inc.* (*AT&T I*), 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019).

C. Criticisms of the Open Offer Are Without Merit.

In an attempt to skirt the reality that the Open Offer fully and adequately addresses the FTC's and customers' concerns with the Transaction, Complaint Counsel tries to muster up threadbare criticisms of the Open Offer's provisions. None have merit.

1. Customer Complaints About the Open Offer Are Unreliable.

As a threshold matter, several customers who have criticized the Open Offer are not credible witnesses regarding the Open Offer's terms, and their complaints should be discredited accordingly. Many of the Open Offer's critics are barely even familiar with its terms. The CEO of Exact, Mr. Kevin Conroy, for example, had not even read the Open Offer at the time of the trial and, beyond what counsel described to him, knew nothing about what the Open Offer requires Illumina to do. (PFF ¶ 1073.) [redacted] Moreover, never in its negotiations with Illumina did Guardant indicate that it viewed the amended supply agreement as unenforceable or worthless. (PFF ¶ 1075.5.) Thus, Mr. Getty's assertions to that effect about the Open Offer—which provides customers with *even more* extensive protections than Guardant's agreement—are

not credible. (PFF ¶ 1047 (providing for biannual audits, which are not available under Guardant's amended agreement).)

Similarly, many of the complaints about the Open Offer come not from customers with genuine concerns about its efficacy, but rather from customers who intend to use the FTC investigation to pressure Illumina into accepting unreasonable demands. [redacted] Relatedly, in individual supply agreement negotiations, many customers made exorbitant requests that clearly evidenced gamesmanship. [redacted]

[redacted] thus do not represent good-faith criticisms. They illustrate the opportunistic use of FTC scrutiny to exert negotiating pressure on Illumina.

[redacted] Given the fact that the Open Offer addresses any genuine foreclosure concerns relating to issues like access to products and fair pricing, the testimony of customers like FMI makes sense. By contrast, the overblown complaints about the Open Offer by uninformed customers or those who seek to extract unreasonable contract terms from Illumina have been discredited and should be disregarded.

2. The Theory of Incomplete Contracting Shows that the Open Offer Is Likely To Be Effective Over the Entire Twelve-Year Term.

Certain customers and Complaint Counsel's expert suggest that, no matter what terms the Open Offer includes, ***no contract*** could effectively prohibit foreclosure because no contract can anticipate every circumstance that might arise over a twelve-year term. While it is

true that no contract can anticipate every contingency, this criticism misses the point. The theory of incomplete contracting holds that, even though parties to a contract may not be able to foresee every possible circumstance that might arise during the life of a contract, parties can still create effective contracts and economists can still evaluate those contracts to determine whether they adequately address the parties' goals. (PFF ¶¶ 1075–1075.3.) Courts have recognized as much in the vertical merger context by approving contractual solutions to alleged anticompetitive harms. *See, e.g.*, *AT&T, Inc.*, 916 F.3d at 1041 (affirming the district court's approval of merger given defendant's offer of arbitration and no-blackout agreements). Here, the Open Offer completely addresses the competitive concerns that would likely arise over a twelve-year term. (PFF ¶ 1083.) It does so in part by using flexible terms that can respond to changed circumstances. For example, rather than prescribing specific types of assistance, the FDA provision in the Open Offer requires Illumina to provide whatever documentation is needed for FDA approval. (PFF ¶¶ 1083.1–1083.2.) This allows the provision to be effective even if FDA requirements change over time.

[redacted] And, perplexingly, while Dr. Scott Morton professes no confidence in the Open Offer's ability to protect GRAIL's putative rivals, she assumes that, absent the merger, sophisticated contracts could be written that would enable the efficiencies of the merger. (PFF ¶¶ 1078.2.) These inconsistencies betray the error in any argument that a contract or offer is inadequate because it does not cover every possible contingency. What matters is that the Open

Offer provides the economically necessary set of terms to provide customers with long-term protections from foreclosure. (PFF ¶¶ 1077.)

3. Under the Open Offer, Illumina's Incentives Remain Focused on Expanding Access to NGS for All Customers.

Complaint Counsel also maintained that the Open Offer does not effectively curb Illumina's alleged incentives to foreclose GRAIL's putative rivals. But this is wrong for at least two reasons. *First*, regardless of any incentives, the most important element in evaluating the Open Offer's efficacy is whether it, in fact, takes away Illumina's ability to foreclose. (PFF ¶¶ 1082–1082.1.) And, it does. As explained above, the comprehensive set of constraints removes any ability for Illumina to meaningfully disadvantage GRAIL's putative rivals. *See supra* Section 1.B.

Second, even if the Open Offer failed to remove Illumina's ability to foreclose GRAIL's putative rivals, Illumina remains incentivized to expand access to NGS for all of its customers and the Open Offer serves to reinforce these procompetitive incentives. The core of Illumina's business continues to come from selling sequencing instruments and consumables. (PFF ¶¶ 850–850.1.) Illumina is thus incentivized to treat its customers fairly so that it does not lose their business to alternative providers. The Second Circuit confronted a similar situation in *Fruehauf Corp. v. FTC*, 603 F.2d 345 (1979). There, a manufacturer of truck trailers, Fruehauf Corporation ("Fruehauf"), acquired Kelsey-Hayes Company ("Kelsey"), one of Fruehauf's suppliers of heavy-duty wheels ("HDWs"). *Id.* at 347. After the acquisition, Fruehauf promised that Kelsey would continue its historic practice of allocating supply shortages pro rata among all of its customers. *Id.* at 354–55. The Court explained that, while "[o]ne might reasonably question the weight to be given to [Fruehauf's] self-serving assurances that Kelsey would allocate [p]ro rata if the need arose", Fruehauf's promises "need not rest upon some

philosophical commitment to egalitarianism since it could also make sound business sense. If Kelsey deprived its regular customers of a proportionate share of HDWs in times of shortage it would risk their retaliating by shifting to competing suppliers not only their purchases of HDWs but of other products presently bought from Kelsey, which could cause it greater economic harm." *Id.* at 355. In part based on this reasoning, the Court held that the merger was not substantially likely to lessen competition. *Id.* Similarly here, the promises Illumina has made in the Open Offer "need not rest upon some philosophical commitment to egalitarianism" because they "make sound business sense" given that customers could retaliate against any breach of the Open Offer by "shifting to competing suppliers". *Id.* Moreover, as Dr. Scott Morton acknowledges, complying with the Open Offer will have a favorable impact on Illumina's reputation and will help it avoid enforcement actions by MCED test developers. (PFF ¶ 1082.3.) Thus, not only does the Open Offer constrain Illumina's ability to foreclose GRAIL's putative rivals; it also helps ensure that Illumina remains incentivized to assist, not disadvantage, MCED test developers.

4. Illumina Cannot Evade the Provisions of the Open Offer.

Left without any credible criticisms of the substance of the Open Offer, Complaint Counsel, its expert and certain customers are forced to argue that Illumina can simply avoid the Open Offer's provisions. This argument, like the others, is a non-starter.

Now that Illumina has made the Open Offer available to its customers, it cannot revoke it. The Open Offer clearly states that "[t]his irrevocable offer is binding on Illumina." (PFF ¶ 994.1.) Under New York contract law, which governs the Open Offer (PFF ¶ 994.1), Illumina is "firmly bound to hold [the Open Offer] open for the agreed time" of six years from the close of the Transaction. *Silverstein v. United Cerebral Palsy Ass'n of Westchester Cnty.*, 232 N.Y.S.2d 968, 968 (N.Y. App. Div. 1st Dep't 1962). If Illumina attempted to revoke the

Open Offer prior to the end of the six-year term, customers could also sue Illumina under the promissory estoppel doctrine because the Open Offer is a clear and unambiguous promise, *see Ripple's of Clearview, Inc. v. Le Havre Assocs.*, 452 N.Y.S.2d 447, 449 (N.Y. App. Div. 2d Dep't 1982), and it is reasonably foreseeable that current or prospective customers of Illumina would rely on the commitments set forth in the Open Offer, *see Villnave Constr. Servs., Inc. v. Crossgates Mall Gen. Co. Newco, LLC*, 1612 N.Y.S.3d 480, 486 (N.Y. App. Div. 3d Dep't 2022). Illumina executives have made several public commitments to the Open Offer, including under oath at this trial, thus giving reasons even beyond New York contract law for Illumina to adhere to the Open Offer. (PFF ¶ 994.2.) Accordingly, Illumina is bound to hold the Open Offer open for six years after the close of the Transaction.

Once customers sign the Open Offer, they receive the benefit of enforcement provisions that guarantee Illumina cannot escape its obligations. As explained above, these enforcement provisions are more than adequate to ensure Illumina's compliance. *See supra* Section 1.B (Enforcement). Critics of the Open Offer assert that the enforcement provisions are insufficient because the Open Offer cannot be effectively audited and because arbitration is too costly and time-consuming. Their arguments in this regard are unpersuasive. First, Mr. Robert Rock, an expert on audits, testified extensively about the steps that Illumina can follow to ensure that the biannual external audits under the Open Offer are effective. (PFF ¶ 1103, 1103.2–1103.7.) Illumina has already engaged outside consultants to operationalize the terms of the Open Offer, which will help enable maximally effective audits. (PFF ¶ 1052.) Contrary to the suggestions of the Open Offer's critics, then, the Open Offer can be audited by following a simple, step-by-step procedure that is already underway.

Second, the arbitration term of the Open Offer is not too costly or expensive. As with any business decision, customers will evaluate costs and benefits and undertake arbitration in circumstances where it is cost-effective. (PFF ¶ 1105.) Additionally, Illumina aims to lower the cost and time spent on any arbitration as much as possible. (PFF ¶ 1105.2.) It is Illumina's goal to get through any arbitration as expeditiously as possible, including by allowing for steps in the arbitration process to occur in parallel. (PFF ¶ 1105.2.) Further, in any arbitration arising out of the Open Offer, the arbitrator is empowered to award ***any relief necessary*** to make the customer whole and must follow the Commercial Arbitration Rules of the American Arbitration Association (AAA). (PFF ¶ 1055.) Under the AAA rules, arbitrators may award attorneys' fees if requested by the parties to the arbitration. AAA, COMMERCIAL ARBITRATION RULES AND MEDIATION PROCEDURES 28, R-47 (d)(ii) (2013). Finally, even before any binding arbitration, the Open Offer allows for an immediate dispute resolution process. (PFF ¶ 1054.3.) Under this process, Illumina and the customer each designate an individual to meet either in person or by phone to resolve the dispute in a final and binding fashion. (PFF ¶ 1054.3.) This helps address concerns about the possible time and expense of arbitration, especially given Illumina's interest in resolving any disputes under the Open Offer quickly. (PFF ¶¶ 1054.4–1054.5.) Thus, the criticisms of the Open Offer's enforcement provisions are overstated.

Even aside from the Open Offer's formal provisions, extrinsic aspects of the Open Offer help ensure that Illumina will abide by its terms. (PFF ¶ 998.) Specifically, all of the terms of the Open Offer are publicly available on Illumina's website, as is the cover letter enclosing the Open Offer, which notes that the purpose of the Open Offer is to allay customer concerns and constrain conduct that could disadvantage rivals. (PFF ¶¶ 998.1–998.2.) Given the public scrutiny of the Open Offer, if Illumina failed to follow through on its commitments, it

would face tremendous backlash from its customers. Accordingly, it would be a mistake "to conclude that [Illumina] would (much less could) retreat from the commitment [of the Open Offer] in light of the apparent reputational costs of doing so—costs that would imperil future negotiations in a marketplace with repeat players." *AT&T I*, 310 F. Supp. 3d at 241 n.51. Conversely, as Dr. Scott Morton acknowledges, compliance with the Open Offer will have a favorable impact on Illumina's reputation. (PFF ¶¶ 998.5.)

As a result, given the extensive and effective enforcement provisions, as well as the extrinsic factors that compel Illumina's compliance, there is no basis for the claim that Illumina could or would avoid its obligations under the Open Offer.

D. [redacted]

Rather than engaging with Illumina on the terms of its Proposed Consent Order, however, Complaint Counsel dismissed the offer as inadequate. Again, however, Complaint Counsel is mistaken. Consent decrees are effective measures for resolving antitrust disputes and have been used by the FTC and other regulatory agencies for many years. (PFF ¶ 1072.1.) The Open Offer's provisions are consistent with consent decrees adopted by the FTC in the past. (PFF ¶¶ 1000.3, 1103.3); *see, e.g.*, *Broadcom Inc.*, FTC Docket No. C-4622 (Aug. 17, 2017); *Evanston Northwestern Healthcare Corp.*, FTC Docket No. 9315 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Docket No. C-4652 (June 5, 2018); *PepsiCo, Inc.*, FTC Docket No. C-4301 (Sept. 27, 2010); *Sycamore Partners II*, FTC Docket No. C-4667 (Jan. 25, 2019). Complaint Counsel has provided no compelling reason why Illumina's Proposed Consent Order's terms differ from those of past consent decrees in a way that suggests the Proposed Consent Order would be less effective.

Consent orders or judgments subject to certain conditions are especially appropriate when, as here, defendants are willing to be legally bound by such orders or conditions. *See, e.g.*, *Butterworth*, 946 F. Supp. at 1298 (denying plaintiff's motion for injunction when "[d]efendants [were] willing to enter into a consent decree making the Community Commitment legally binding") (consent decree signed by court one month later); *United States v. Comcast Corp.*, 808 F. Supp. 2d. 145, 147 (D.D.C. 2011) (approving merger where "defendants agreed to abide by the provisions of a proposed Final Judgment that would allow the merger to go forward, while also putting into place certain remedies for what the Government alleged was anti-competitive behavior") (final judgment entered on same day); *Anaconda Co. v. Crane Co.*, 411 F. Supp. 1210, 1218 (S.D.N.Y. 1975) (denying plaintiff's request for preliminary injunction in light of defendant's consent order that the Court determined

was "sufficiently broad to prohibit any unilateral actions by Crane . . . which may have the effect of lessening competition with Anaconda"); *AT&T II*, 916 F.3d at 1041 (affirming the district court's approval of merger given defendant's voluntary offer of arbitration and no-blackout agreements that were "irrevocable" and "legally enforceable"); *United States v. Metro Denver Concrete Ass'n*, No. C-2478, 1972 WL 520 (D. Colo. Feb. 28, 1972) (final judgment entered pursuant to a consent decree executed by the defendants).

Even if Complaint Counsel refuses to engage with Illumina's proposal, the proposal itself is evidence that GRAIL's putative rivals will not be foreclosed because the proposal demonstrates Illumina's pro-competitive incentives. This offer represents the latest in a series of steps since the announcement of the Transaction geared toward making Illumina's customers secure post-merger. (*See* Section 1.A *supra*.) First, Illumina engaged in extensive outreach to understand customers' concerns with the Transaction. (PFF ¶¶ 987–987.2.) After that, Illumina published the Open Offer to allay these concerns. (PFF ¶ 991.) Although the original Open Offer completely addressed any ability of Illumina to foreclose GRAIL's putative rivals, Illumina subsequently dev[redacted] additional protections to make it even better and issued an addendum on September 8, 2021. (PFF ¶ 996.) Then, in response to the concern that Illumina could avoid its obligations under the Open Offer, it presented the FTC with a Proposed Consent Order. (PFF ¶ 1070.) Even now, Illumina remains open to improving the terms of the Open Offer and Proposed Consent Order (PFF ¶ 1054.2) because it sees the immense benefits of this Transaction and is determined to achieve these benefits without creating any anticompetitive harms. All of these actions show that Illumina has been and remains committed to protecting its relationships with customers after the Transaction.

Complaint Counsel's refusal to engage with Illumina on the Open Offer and on the Proposed Consent Order is thus misguided. Illumina has extended an offer to its customers that addresses, point-by-point, every concern raised about the Transaction. It allows for the benefits of the Transaction and prevents any anticompetitive harms. It ensures Illumina's compliance through a two-pronged audit-and-arbitration approach, reminiscent of the enforcement provisions from remedies approved in past vertical mergers. And to the extent that Complaint Counsel still has concerns about the Transaction or about the Open Offer's ability to constrain Illumina's conduct, Illumina has proposed an effective consent decree that would be enforced by the FTC itself. Complaint Counsel has not shown and cannot show how these robust protections fail to prevent any anticompetitive harm from the Transaction.

IV. THE BENEFITS OF THE TRANSACTION MORE THAN OFFSET THE ALLEGED HARM.

Even if the Transaction could be said to give Illumina the ability and incentive to harm competition, and even if the Open Offer were unable to eliminate the risk of harm, the benefits of the deal easily outweigh the alleged harm. The Transaction will result in numerous, merger-specific benefits; in particular, it will save many thousands of lives (in the U.S. and throughout the world) and billions of dollars.

While Complaint Counsel has argued that the efficiencies of the Transaction are unsubstantiated, each was supported by every Illumina and GRAIL witness to testify about them. (PFF ¶ 1107.) That includes the trial testimony of Francis deSouza (President and CEO of Illumina), Dr. Alex Aravanis (Chief Technology Officer of Illumina and former head of R&D at GRAIL), Dr. Phil Febbo (Chief Medical Officer of Illumina), Ammar Qadan (Vice President and Global Head of Market Access at Illumina), Jay Flatley (former CEO and Chairman of the Illumina Board of Directors at the time of the Transaction), Hans Bishop (then-CEO of GRAIL),

Dr. Joshua Ofman (President and Chief Medical Officer and then-Head of External Affairs of GRAIL), Aaron Freidin (Chief Financial Officer and then-Senior Vice President of Finance at GRAIL) and Dr. Arash Jamshidi (then-Senior Vice President of Data Sciences at GRAIL). (PFF ¶ 1108.) Complaint Counsel either conducted no cross examination of these witnesses on the Transaction's benefits or its questioning readily affirmed the efficiencies. (PFF ¶ 1109.)

What is more, the former Chairman of Illumina, Jay Flatley, testified—without contradiction—that the Illumina Board came to the unanimous conclusion that the Transaction will generate specific efficiencies, including accelerating the adoption of Galleri, streamlining the supply chain, streamlining operations, accelerating international expansion, generating R&D efficiencies and, most importantly, saving lives. (PFF ¶ 1110.) At the time the Illumina Board approved the Transaction, the Illumina Board included a Nobel Laureate, a former FDA commissioner, financial experts and experienced veterans in the biotech industry. (PFF ¶ 1111.) Each of the individuals came to his or her independent conclusion, based on a wealth of experience, that the Transaction will generate efficiencies. (PFF ¶ 1112.) On the flip side, Complaint Counsel offered no fact evidence—not a single witness—to say otherwise. (PFF ¶ 1116.) The proof of efficiencies is conclusive and uncontroverted. (PFF ¶ 1116.)

A. The Reunion of Illumina and GRAIL Will Save Lives

For all the parties' disagreements, it is undisputed that accelerating consumer access to Galleri will save lives. (PFF ¶ 1117.) All agree that cancer screening saves lives. (PFF ¶ 1117.1.) All agree that accelerating the adoption of a cancer screening test will save still more lives. (PFF ¶ 1117.2.) And the unrefuted evidence shows that reuniting Illumina and GRAIL will accelerate the adoption of the Galleri test. (PFF ¶ 1117.3.)

Cancer Screening Saves Lives. Cancer kills more than 600,000 people annually in the U.S. and more than 9.5 million people annually worldwide. (PFF ¶ 1118.) Numerous fact

witnesses, including those called by Complaint Counsel, testified that cancer screening will reduce these numbers and save lives. (PFF ¶ 1119.1 (Conroy (Exact/Thrive) Tr. 1737) ("Q. The widespread adoption, sir, of an MCED test, a multicancer early detection test, will save lives. Do you agree with that? A. I do agree with that.").) Complaint Counsel agrees that cancer screening save lives. (PFF ¶ 1119.2.)

Accelerating Screening Tests Will Save More Lives. Accelerating the adoption of a cancer screening test like Galleri will save still more lives. (PFF ¶ 1120.) Every fact witness to address the issue, including witnesses called by Complaint Counsel, testified that accelerating the adoption of a cancer screening test will save lives. (PFF ¶ 1120.1.) For example, Kevin Conroy, the CEO of Exact Sciences, said that "the acceleration of any [cancer screening] test will save lives". (PFF ¶ 1120.1.) Complaint Counsel's experts agreed. [redacted]

[redacted]; PX7139 (Navathe Trial Dep. at 136 ("Q. If more Galleri tests are conducted, more cancers will be found at earlier stages right? A. I think as a hypothetical, holding all other factors constant, yes. Q. And that would be better for patient outcomes; right? A. Yes. Q. It will – specifically, it will extend patients' lives right? A. Yes.")).)

The Transaction Will Accelerate Galleri and Thus Save Lives. Illumina and GRAIL witnesses testified—without refutation—that the reunion of Illumina and GRAIL will accelerate Galleri and save lives in the U.S. and worldwide. (PFF ¶ 1121.1.)

- Francis deSouza, Illumina's President and CEO, testified that "[t]his transaction has the potential to fundamentally dent the mortality curve in cancer and save many, many thousands of lives around the world. Illumina can accelerate global access to this life-saving test by making this test more available". (PFF ¶ 1121.2.)

- Dr. Alex Aravanis, Chief Technology Officer of Illumina and former head of R&D at GRAIL, testified that the transaction "will lead to millions of more tests performed, tens of thousands of additional lives saved, reduction in the cost of the Galleri test, [and] much broader access". (PFF ¶ 1121.3.)

- Dr. Phil Febbo, Chief Medical Officer of Illumina, testified that he recommended the approval of the Transaction because "I do see that earlier detection has the opportunity to save a lot of lives, and when I started looking at the work we were doing, it became very clear to me that Illumina reacquiring GRAIL, bringing GRAIL back into Illumina could accelerate the speed with which patients would have access to that test through multiple activities." (PFF ¶ 1121.4.)

- Jay Flatley, the Chairman of the Illumina Board of Directors at the time of the Transaction, testified that "[t]he board's collective judgment, as we took a final unanimous vote on this, was that not only was this in the interest of our shareholders but that for all the reasons I just discussed, this would have a dramatic impact on the rate with which we could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer." (PFF ¶ 1121.5.)

- [redacted]

- [redacted]

- Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that acceleration of Galleri by Illumina means that GRAIL "will do it faster. We will save more lives". (PFF ¶ 1121.8.)

- [redacted]

[redacted]

The Transaction Is Estimated To Accelerate the Adoption of Galleri by at Least One Year. Although it is difficult to quantify with precision the extent to which the Transaction will accelerate the wide-spread adoption of Galleri, Illumina has conservatively estimated that a reunited Illumina and GRAIL will accelerate Galleri's adoption by at least one year. (PFF ¶ 1122.1 ("We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year").) [redacted]

Acceleration Results in Thousands of Lives Saved. Acknowledging the difficulty of valuing human life in monetary terms but using valuations routinely used by the government, Dr. Carlton testified that the value of an acceleration of one year is at least $37 billion. (PFF ¶ 1123.1.) Dr. Carlton estimated that a one-year acceleration would lead to an additional 10 million tests performed in the U.S. over a nine-year period (2022-2030). (PFF ¶ 1123.2.) As shown in the chart below, Dr. Carlton then used "estimates in the literature about how Galleri testing will save lives" and arrived at a "range . . . from 7,429 to 10,441" lives saved from the acceleration. (PFF ¶ 1123.3.)

Table 3: Baseline tests projected in deal model and impact of one-year acceleration in U.S.

Year	Standalone Tests Sold (Million)	Accelerated Tests Sold (Million)	Additional Tests Sold (Million)	Lives Saved (74 per 100k Tests)	Lives Saved (104 per 100k Tests)
2022	0.1	0.1	0.0	30	43
2023	0.1	0.4	0.3	188	265
2024	0.4	0.9	0.5	374	525
2025	0.9	2.1	1.2	897	1,261
2026	2.1	3.7	1.6	1,207	1,696
2027	3.7	6.1	2.4	1,744	2,451
2028	6.1	7.6	1.5	1,109	1,558
2029	7.6	8.8	1.2	872	1,226
2030	8.8	10.1	1.4	1,007	1,416
Total	**29.9**	**40.0**	**10.0**	**7,429**	**10,441**

Source: Deal Model; Hubbell, et al.

(PFF ¶ 1123.3.) Using a low estimate of $5 million for the value of lives saved, Dr. Carlton estimated a low-end value of the efficiencies of $37 billion. (PFF ¶ 1123.4.)

Dr. Carlton's estimate is conservative. (PFF ¶ 1124.) For example, the estimate uses the lower end of lives saved and the value of lives saved. (PFF ¶ 1124.1.) "If you use the higher estimate [of lives saved], the 10,441, and" the higher estimate of the value of a life saved is "roughly $10 million[,] then you get over $100 billion". (PFF ¶ 1124.1.) In addition, the estimate does not include the value of international acceleration, which would more than double the benefits. (PFF ¶ 1124.2 ("My calculations include U.S. lives only. Acceleration will also save lives in other countries. With a one-year acceleration, an additional 10.4 million tests would be performed outside of the U.S. over the nine-year period 2022-2030. If the lives saved

by these tests are valued the same as lives saved in the U.S., then the total benefits from acceleration would be more than double what I calculate.").)[21]

The Lives-Saved Efficiency Is Unrefuted. [redacted] is directly contradicted by the Department of Health and Human Services and FDA guidance, which states that "the approach for valuing mortality risk reductions is generally based on estimates of the value per statistical life". (PFF ¶ 1126.2.) [redacted] In other words, the Hubbell training set is reliable for the purpose for which Dr. Carlton used it. (PFF ¶ 1126.3 ("As the holdout demonstrated the average performance was

[21] Dr. Carlton's estimate also does not include the fact that acceleration of GRAIL's sales will allow GRAIL to improve the quality of the Galleri test by generating data more quickly. (PFF ¶ 1124.3.)

The size of the lives saved efficiency is also validated by alternative calculation methods. (PFF ¶ 1125.) Dr. Carlton calculated the value of life-years saved by valuing a life year at between $100,000 and $150,000. (PFF ¶ 1125.1.) Using this calculation, the lives saved from a one year acceleration in the U.S. were still valued at least between $11 and $16 billion. (PFF ¶ 1125.1.)

compatible with the cross-validated training set, we use here the training set sensitivities which allow resolution of individual cancer type sensitivities by stage"); PFF ¶ 1126.3 ("My understanding from the article, as well as discussions with Dr. Hubb[ell], is that there is no bias").) And Dr. Navathe's claim that Dr. Carlton should not have assumed perfect compliance with the Galleri testing regime overlooks the fact that this assumption actually makes Dr. Carlton's estimate *more* conservative, not less. (PFF ¶ 1126.4.) Moreover, none of Dr. Navathe's criticisms change the fundamentals of Dr. Carlton's conclusion: thousands of lives will be saved by the Transaction and the value of those lives is in the billions of dollars. (PFF ¶ 1126.5.) None of Complaint Counsel's experts reliably refute this assertion. (PFF ¶ 1126.5.)

Complaint Counsel's economist, Dr. Scott Morton, speculates that, but for the Transaction, other MCED tests currently in development could be better and therefore might result in even more lives saved. (PFF ¶ 1126.6.) However, this argument is not supported by the evidence. Instead, it asks this Court to accept speculation regarding potential MCED tests over factual evidence regarding existing efficiencies from a test that is now in the market and has been subjected to studies upon which the conservative efficiency and lives saved estimates are based. (PFF ¶ 1126.7.) It is undisputed that Galleri is the only NGS-based MCED test on the market. (*See*, *e.g.*, Complaint Counsel Opening Argument Tr. 11 ("[W]e agree that MCED tests is a developing market, meaning, GRAIL is the only company that is offering MCED tests for sale in even a limited capacity")). Also, there is unrefuted evidence that Illumina will accelerate Galleri and thereby save more lives. (PFF ¶ 1126.7.) In contrast, there is no guarantee that any other MCED test will ever be released much less that they will be able to save the same number of lives as GRAIL or save those lives sooner. (PFF ¶ 1126.7.) There is no study comparable to the

Hubbell paper on the impact of any other test in development. (PFF ¶ 1126.7.) Dr. Scott Morton's claim is pure conjecture. (PFF ¶ 1126.7.)

Courts have rejected challenges to mergers generating much less substantial healthcare benefits than those expected to result from this Transaction. *See*, *e.g.*, *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1032 (W.D. Mich. 1996) (concluding that "defendants have persuasively rebutted not only the FTC's prima facie case, but also the FTC's additional evidence of anticompetitive effect" as "[i]n the real world, hospitals are in the business of saving lives . . . Permitting defendant hospitals to achieve the efficiencies of scale that would clearly result from the proposed merger would enable the board of directors of the combined entity to continue the quest for establishment of world-class health facilities"); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 147 (E.D.N.Y. 1997) (holding that "the Government failed to prove that the merger of these hospitals will substantially lessen competition" after finding that the cost savings from the merger may be used "to fulfill [the defendants'] mission to provide high quality health care to economically disadvantaged and elderly members of the community"); *United States v. Carilion Health Sys.*, 717 F. Supp. 840, 845 (W.D. Va. 1989) (rejecting the government's Sherman Act merger challenge after finding that "the planned merger would probably improve the quality of health care in western Virginia").

B. The Reunion of Illumina and GRAIL Will Accelerate Market Access to a Life Saving Test.

To achieve widespread adoption, GRAIL will need to achieve regulatory approval and payor coverage for Galleri. (PFF ¶ 1127.1.) While Galleri was launched in June 2021, it has a long way to go to obtain widespread adoption. (PFF ¶ 1127.2.) GRAIL is a new company with no expertise or experience in achieving regulatory approval and payor coverage for an NGS

test. (PFF ¶ 1127.3.) Illumina, in contrast, has unique experience and capabilities that will enable the acceleration of market access for Galleri. (PFF ¶ 1127.4.) Hence, the reunion of Illumina and GRAIL will substantially accelerate market access for Galleri. (PFF ¶ 1127.5.)

Galleri's Limited Availability. GRAIL launched Galleri as an LDT in June 2021. (PFF ¶ 1128.1.) Galleri is available for $949, a price that many individuals cannot afford. (PFF ¶ 1128.2.) Galleri is not approved by the FDA or covered by CMS or reimbursed by private payors. (PFF ¶ 1128.3.) At the time of the live hearing, Galleri had only had limited sales of approximately three to four thousand tests. (PFF ¶ 1128.4.)

FDA, CMS And Payor Approval Are Necessary for Widespread Adoption. Widespread market access to Galleri will depend on FDA, CMS and payor approval. (PFF ¶ 1129.) Numerous fact witnesses, including third-party witnesses called by Complaint Counsel, testified that widespread adoption of an MCED test like Galleri will require FDA, CMS and payor approval. (PFF ¶ 1129.1.) As Dr. Deverka explained:

- [redacted]
- A novel test like Galleri "needs to have a premarket authorization, so clearance by the FDA. And how that's relevant for payers is that for the Medicare pathway it's actually a requirement to have an FDA-approved or cleared test. And while private payers can choose to pay for a laboratory-developed test, they sometimes pay addition- -- give additional weight to the fact that a test has received FDA approval because it's essentially an imprimatur of quality and that the FDA with its rigorous process has approved the test."

(PFF ¶ 1129.3.) Dr. Scott Morton agreed. As she admitted, [redacted]

[redacted]

GRAIL's Inexperience. GRAIL is inexperienced in obtaining FDA approval, CMS coverage and private payor approval. (PFF ¶ 1130.)

- [redacted]
- Aaron Freidin testified that Illumina has more experience "[c]ompared to what GRAIL's internal capabilities are and what our history is with the FDA today". (PFF ¶ 1130.2.)
- Dr. Aravanis testified that GRAIL has no experience getting FDA approval and payor coverage. (PFF ¶ 1130.3.)
- Dr. Deverka explained "on the Galleri side, to date, their experience is all premarket, and so they don't have extensive – they don't have a track record of successfully bringing a product to payer coverage." (PFF ¶ 1130.4.) [redacted]

Complaint Counsel did not put forward any fact witness that disagreed with this assessment, and its economic expert agreed that GRAIL lacks such experience. (PFF ¶¶ 1130.5–1130.6.)

Illumina's Experience and Expertise. Illumina is highly experienced in obtaining FDA approval, CMS coverage and private payor approval for NGS products. (PFF ¶ 1131.) Numerous witnesses testified to Illumina's experience and expertise in these areas. (PFF ¶ 1132.)

- Mr. deSouza testified that "we have now, you know, closing in on about ten years' experience working with the FDA. We have since got other sequencers approved. . . . And on the test side, we're working on getting approval for our TSO 500, we're working on getting approval for our NIPT assay here in the U.S., and we're looking at getting approval for a genetic disease diagnosis workflow as well." (PFF ¶ 1132.1.) With respect to payor coverage, Mr. deSouza testified Illumina "has been working

with payers in the U.S. and around the world, again, for almost a decade. We have a very talented team that has expertise in working with payers and is -- and has the right innovation focus to come up with new models to accelerate the evidence generation needed to get payers on board." (PFF ¶ 1132.2.)

- Dr. Aravanis testified that "Illumina received the first FDA clearance for a next-generation sequencer. It's received over 70 clearances and registrations around the world in 45 countries. It's received multiple clearances and a PMA approval in the United States". (PFF ¶ 1132.3.) He also testified that "Illumina has pioneered multiple approaches to market access, resulting in over 100 million additional patients worldwide covered for whole genome testing for genetic disease over the last two years. In the United States we have now achieved 200 million people who can receive coverage for comprehensive genomic profiling using NGS technology. These were largely driven by Illumina's market access efforts". (PFF ¶ 1132.4.)

- Ammar Qadan, Vice President and Global Head of Market Access at Illumina, provided a detailed overview of Illumina's extensive market access capabilities and the success they have had working with payors in the NGS space. (PFF ¶ 1132.5.)

- [redacted]

- Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "Illumina has those resources to do those things and have demonstrated doing it in the past". (PFF ¶ 1132.7.)

- Dr. Deverka testified that Illumina has "a track record of a market access team having generated the requisite evidence of clinical utility and engagement with payers, both in the U.S. and internationally, to support the use of next-generation sequencing-based tests, so it's really their – their objective track record". (PFF ¶ 1132.8.)

Complaint Counsel did not put forward any fact witness that disagreed with this assessment, and its expert witnesses lack the expertise to opine on the issue. (PFF ¶ 1132.9.)

The Transaction Will Accelerate FDA, CMS and Payor Coverage of Galleri.

Numerous Illumina and GRAIL fact witnesses testified that the reunion of Illumina and GRAIL will accelerate Galleri's path to FDA approval and CMS and private payor coverage (PFF ¶ 1133):

- Francis deSouza testified that: "We also have deep expertise working with payers. We have created innovative programs like risk-sharing agreements with insurance companies where we contribute resources and offer a test to a segment of the population to gather the clinical data as well as the economic data to build the case for the insurance company to cover the test. . . . Now, that's stuff we can just plug the GRAIL, you know, work into and accelerate the adoption of GRAIL, so there's a lot of work we can do on market access. . . our teams have deep experience, nearing now a decade, on working with regulators to get cleared tests and to get cleared sequencers. We're working that in oncology now and we're working that for genetic disease now and hope to get the first -- you know, to progress that as well". (PFF ¶ 1133.1.)

- Dr. Aravanis testified that: "Illumina has made applications and has multiple pending applications for first-in-kind products for next-generation sequencing. In doing that, it's broken new ground working with the FDA on how to develop applications for these types of processes. They're very complex diagnostics. The applications are complex, and it's learned a tremendous amount in doing that and incorporated those into the current processes and templates for making applications. Those benefits will be conferred to GRAIL as part of the acquisition. . . apply the same approaches that Illumina used in other areas where it's increased market access and reimbursement." (PFF ¶ 1133.2.)

- Dr. Febbo testified that "I've seen our regulatory team. I've seen our broad teams come together to address multiple challenges, regulatory challenges as well as others. I know the incredible depth -- how the incredible depth of expertise we have at Illumina is brought to bear and how we can motivate and really engage and execute on strategies to address challenges and to accelerate those timelines . . . We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year". (PFF ¶ 1133.3.)

- Ammar Qadan testified that "Through some of the partnerships that we have today, we will be able to accelerate the development, for example, with commercial payers in the U.S. We -- in fact, we can do a lot. We can also accelerate, though it's not my area of expertise, but we can accelerate hopefully the regulatory approval, resulting in an accelerated path for CMS coverage and reimbursement." (PFF ¶ 1133.4.)

- Jay Flatley testified that Illumina "has the ability to accelerate the adoption of this test or the approval of the test through the FDA. We also have the ability, because of the size and scope of the company, to establish reimbursement much more quickly than GRAIL would have the ability to do." (PFF ¶ 1133.5.)

- Hans Bishop testified that "deep expertise in interacting with regulators derisks and maybe speeds up the speed at which we can get the regulatory approvals, which are often – certainly that's true in the United States – a prerequisite to getting reimbursement. . . . [W]e have to be concerned about government and payers' ability to pay, and being part of Illumina will help us accelerate the speed at which we can drop the price of our tests." (PFF ¶ 1133.6.)

- [redacted]

- Aaron Freidin testified that "a large inflection point to creating value and saving lives is going to be getting broad reimbursement. And this population we're addressing is between 50 and 80, of which, you know, the majority -- a lot of those people are on public government pay, whether it's Medicare or something else. So to go down that path we'd have to have a PMA and get reimbursement, and so on. You know, Illumina has those resources to do those things and have demonstrated doing it in the past." (PFF ¶ 1133.8.)

- [redacted]

Complaint Counsel did not present any contrary fact witness testimony, and none of its experts are qualified to address the subject. (PFF ¶ 1133.22.)

One example, not disputed in the record of how Illumina can help GRAIL is the creation of quality management systems. [redacted] As Dr. Febbo testified, Illumina has a quality management system that is compliant with the requirements of the FDA and foreign regulators. (PFF ¶ 1386.) Illumina's quality management system has taken seven years to develop and has undergone "multiple audits by the agency, the FDA, as well as international agency, because we have quality systems to support our FDA applications, as well as to support international regulatory requirements . . . Each time we've done very well, but each

time the auditors have found ways to do even better." (PFF ¶ 1386.) [redacted]

[redacted]

Numerous witnesses testified that Illumina's experience and expertise in developing such a quality management system would accelerate Galleri's compliance with regulatory requirements and therefore its scaled commercialization:

- Dr. Febbo testified that Illumina has "had a quality management system longer than GRAIL's been a company, and so those -- that learning, that evolution, and those -- those procedures and documentations that are foundational to the quality systems, as well as some of the software infrastructure, can be incorporated in the leverage to GRAIL's benefit." (PFF ¶ 1386.)
- Dr. Aravanis testified that "Illumina's plan is to give GRAIL capabilities that are known to be a gap, for example, a sophisticated quality management system, GRAIL will need that". (PFF ¶ 1330.)
- [redacted]

Echoing the unrefuted fact testimony, Dr. Deverka testified that the reunion of Illumina and GRAIL will accelerate GRAIL's FDA approval, CMS coverage and payor coverage. (PFF ¶ 1133.23.) Specifically, Dr. Deverka testified that Illumina's relationships with health systems and payors, its knowledge of payor evidence expectations, and its ability to invest in large prospective studies that can be replicated across settings contribute "in a positive way such that in the aggregate there is a strong likelihood that market access will be accelerated. It would be more likely than not." (PFF ¶ 1133.24.) In addition, "[i]f Illumina's resources and prior experience dealing with the FDA are brought to bear with the merged companies that I predict that the -- that could accelerate regulatory approval for Galleri, which would then have the downstream impact of further accelerating payer and Medicare coverage." (PFF ¶ 1133.25.)

The following table compares GRAIL's and Illumina's capabilities in relevant respects and summarizes how the reunion of the companies will accelerate FDA, CMS and private payor coverage:

Capability	GRAIL	Illumina	Expected Efficiencies
Dedicated staff	[redacted]	13 focused on market access; 18 in medical affairs; 17 in clinical affairs; 23 in regulatory affairs; 11 in biostatistics	[redacted]
Experience with private and public payors	[redacted]	Extensive and international. Established coverage track record for multiple NGS test categories (not in CA screening tests)	[redacted]
Health system partnerships	[redacted]	Extensive and international. Track record of success with NIPT, CGP and RUGD	[redacted]
De-risking of reimbursement challenges	[redacted]	Harvard Pilgrim/NIPT case Harvard Pilgrim/WGS case Queensland Australia WGS for RUGD case	[redacted]
Regulatory experience with PMA	[redacted]	Extensive	[redacted]

Capability	GRAIL	Illumina	Expected Efficiencies
Distributed version of test (requires FDA/regulatory approval)		Area of established expertise for Illumina	
Global presence and expertise		Extensive	
Resources to support appropriate real-world use of Galleri, fit into clinical workflow		Experience with educating patients and providers through pre-competitive collaborations (CAPS). Existing partnership with Genome Medical providing education to individuals, health care providers, and employers nationwide	
Value assessment methods development		Experience with funding methods research for value assessments of NGS-based tests (GEECS)	
Technical solutions such as process efficiencies working with laboratories, supply chains and automation		Extensive	

(PFF ¶ 1133.26 (explaining how each of the factors in the above table contribute to Illumina's ability to accelerate Galleri).)

Evidence of Regulatory and Market Access Efficiencies Is Unrefuted. Complaint Counsel does not dispute that Galleri is far from being widely available. (PFF ¶ 1134.1.) Nor does Complaint Counsel dispute that GRAIL has limited regulatory and market access capabilities. (PFF ¶ 1134.2.) Instead, it relies on the testimony of two purported experts, Dr. Rothman and Dr. Navathe, for the proposition that Illumina's ability to accelerate Galleri is not properly substantiated. (PFF ¶ 1134.3.) However, neither Dr. Rothman nor Dr. Navathe has relevant expertise to assess these efficiencies. (PFF ¶ 1134.4 (Navathe admitting that he lacks expertise in seeking FDA approval for an MCED test, how the FDA will evaluate an MCED test, seeking payor coverage for an MCED test and how payors will evaluate an MCED test); PFF ¶ 1134.4 (Rothman admitting that he lacks expertise with respect to FDA approval or payor reimbursement).) Dr. Navathe also made clear that he does not have an opinion on the expected timing of Galleri with or without the Transaction and that he had no opinion on acceleration. (PFF ¶ 1134.5 (Navathe testifying that he "would not be able to predict timing" and has not drawn any conclusion of his own as to when Galleri is likely to get FDA approval with or without the Transaction).) Moreover, neither Dr. Navathe nor Dr. Rothman attempts to undermine the undisputed testimony described above. (PFF ¶ 1134.6.)

[redacted] However, they are, of course, unqualified to speak to Illumina's state of mind. *Kruszka v. Novartis Pharm. Corp.*, 28 F. Supp. 3d 920, 937 (D. Minn. 2014) ("Expert testimony on 'the intent, motives, or state of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise.'");

Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d 420, 442 (E.D.N.Y. 2011) ("to the extent [an expert] seeks to opine on the 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred,' such testimony is inadmissible"). Moreover, unrefuted fact witness testimony (presented at trial) shows Illumina will benefit from acceleration (PFF ¶ 1134.8 (noting that a potential transaction would both accelerate adoption of screening market and increase share of revenue)), and that Illumina intends to implement plans to accelerate Galleri. (PFF ¶ 1134.8.) Complaint Counsel's experts ignored this testimony altogether. (PFF ¶ 1134.8.)[22]

Increasing consumer access to a product has been found to outweigh purported anticompetitive harms in other cases—and in those cases, the product was not a test that saves lives. *See*, *e.g.*, *United States v. Crocker-Anglo Nat'l Bank*, 277 F. Supp. 133, 139, 191 (N.D. Cal. 1967) ("[E]ven had a substantial lessening of competition occurred as a result of the merger of defendant banks, such anticompetitive effects were clearly outweighed in the public interest" in part because the merger "caused an immediate increase in the number of statewide banks competing within the state"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 208–09 (S.D.N.Y. 2020*)* (denying the government's request for an injunction to block the merger after considering that the proposed merger would allow "New T-Mobile to support additional subscribers at reduced marginal costs" by creating "an 'inordinate amount' of new supply in the market"); *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 98 (N.D. Ill. 1981) (denying the FTC's request for injunction in part because the acquiring company, "an aggressive marketer of

[22] [redacted] However, speculation regarding future legislation does nothing to undermine the acceleration Illumina can create today, and Dr. Navathe pointed to no evidence that the potential legislation would actually benefit GRAIL in the same ways the Transaction would. (PFF ¶ 1134.9.)

flame retardants internationally", would help the international market gain access to the acquired company's products).

C. Reuniting Illumina and GRAIL Will Lead to R&D Efficiencies.

In addition to accelerating market access, the Transaction will lead to significant R&D efficiencies, through the combination of GRAIL's expertise in methylation, data science and software development and Illumina's complementary expertise in sequencing and bioinformatics. (PFF ¶ 1136.) Respondents presented extensive fact testimony in support of this efficiency, whereas Complaint Counsel presented no fact witness to refute it. (PFF ¶ 1137.)

GRAIL's Limited R&D Resources. GRAIL is a relatively small company without the resources to focus on all of the R&D projects that it might otherwise be interested in pursuing and for which its technology may be able to unlock substantial discoveries that improve human health. (PFF ¶ 1138 ("GRAIL is a company with much more limited resources than what Illumina has, and as such, they were appropriately focused on delivering the Galleri test to the market and getting that as advanced as they possibly could"); PFF ¶ 1138 ("The investments [GRAIL] need[s] to continue to make in R&D continue to be very significant.").)

Illumina's R&D Resources and Capabilities. Illumina is a larger company with the financial resources to focus on R&D. (PFF ¶ 1139.) In fact, R&D is a core component of Illumina's business. (PFF ¶ 1139.1 ("Q. . . What role does R&D play in Illumina's business generally? A. R&D is absolutely critical at Illumina. Q. Why is that? A. We believe that innovation is going to be critical to, you know, unlock the future markets for genomics, that to unlock the next set of markets we need to continue to deliver lower prices into the market.").)

Illumina spends "over $600 million in R&D" annually "which is about twice as much as a percentage of our revenue on R&D as the industry average". (PFF ¶ 1139.2.).[23]

The Transaction Will Lead to R&D Efficiencies. The reunion of Illumina and GRAIL will lead to significant R&D efficiencies both related to the Galleri test and related to other technologies. (PFF ¶ 1140.) As Jay Flatley testified "We had some opportunities in the R&D side, because when you put brilliant people together like we have at GRAIL and Illumina, sparks fly." (PFF ¶ 1140.1.) Illumina and GRAIL witnesses testified—without contradiction—that Galleri-specific efficiencies will arise from the reunion of Illumina and GRAIL. (PFF ¶ 1141.)

- Francis deSouza testified that: "Our team has deep experience over -- over a decade now in optimizing workflows in the processing of genomic tests. We have been running genomic tests at scale for over a decade now. What that means is our R&D teams are very good at optimizing, you know, how samples come in, so sample accessioning, how samples are prepared for sequencing, so both the sample extraction as well as library preparation. And then our teams are very good at creating high-throughput bioinformatics pipelines to process the data, and so our teams are very good at creating lower-cost, high-throughput workflows to process samples, and that will benefit Galleri." (PFF ¶ 1141.1.)

- Dr. Aravanis testified that: "So Illumina is developing applications in multiple areas: noninvasive prenatal testing, genetic disease testing, therapy selection. We believe that some of those innovations that we're making in those other areas we will be able to apply also to future versions of the Galleri test, improving the performance and, therefore, increasing the clinical value of the test. Another type of R&D efficiency will be to lower the cost of the Galleri test faster. Illumina has significant experience and capabilities in miniaturizing assays, simplifying assays, developing new components for assays that can lower cost, internalizing manufacturing of expensive components, and by internalizing the manufacturing of them, reducing the cost of the overall test. Illumina can manufacture its own enzymes and, therefore, this makes the internalization and manufacturing at lower cost possible." (PFF ¶ 1141.2.)

[23] Illumina has been widely recognized for its R&D work. (PFF ¶ 1139.3 (Illumina has been "recognized as one of the hundred most influential companies by TIME. . . . MIT Technology Review recognized us as the number one smartest company in the world a while ago. So we've received a number of awards over the last few years for our R&D work.").)

- Dr. Febbo testified that: "Well, what I've seen and I'm excited about occurring as the companies come together is that as you expand your testing, as you scale testing and you test hundreds, thousands, tens of thousands of patients, you end up getting data that really helps you understand the test to a degree that's even deeper than initially. It also gives you data where you can bring in your biostatisticians and biostatistics reports to me, you can bring in your -- you know, your -- your medical experts, and together to work with your product development folks that is in core R&D under Alex Aravanis and look at those signals and look at how to improve the test itself, improve the performance, improve the efficiency." (PFF ¶ 1141.3.)

- Jay Flatley testified that the Board of Directors of Illumina determined that "we could take advantage of the data that's coming from the international expansion, integrate that data, and use the deep learning algorithms to improve the accuracy of the Galleri test and to improve the number of cancers that it -- that it addresses. So we would accelerate the improvement of the Galleri test on the one hand. (PFF ¶ 1141.4.)

- Hans Bishop testified that "ongoing access to funding is more secure as part of a large, successful, profitable company, and I believe that Illumina, as an outstanding technical innovation company, deeply understand the importance of ongoing investment in research and development. That's how they've been successful, by continuing to do that. So I believe that the resources that we need to be reliably continuing to make those sorts of investments are greatly secured. I also believe that certain technical abilities that Illumina have." (PFF ¶ 1141.5.)

- [redacted]

Complaint Counsel did not even try to undermine this testimony through cross examination. It stands unrefuted. (PFF ¶ 1141.7.)

Similarly, party witnesses have testified that the Transaction will generate a number of non-Galleri-related R&D efficiencies. (PFF ¶ 1142.)

- Francis deSouza testified that: "We believe that . . . once we're allowed to merge, we will bring our R&D teams together and immediately start the work necessary to identify the genomic biomarkers in blood for other conditions, like fatty liver disease, neurological conditions like Alzheimer's and Parkinson's. We believe . . . we will get

the teams working on it, and we would love to get a blood test screen for those conditions in addition to this cancer screen." (PFF ¶ 1142.1.)

- Dr. Aravanis testified that: "There's a couple ways that we think the transaction will lead to R&D benefits to the larger Illumina. One is novel discoveries. So our experience, for example, in noninvasive prenatal testing is that when you operate a clinical test as a large service, you will have additional findings. Those could give insights into other types of diseases that GRAIL's technology could be useful for. For example, fatty liver disease or neurodegenerative disease. Those are other applications Illumina would pursue. In addition, we've found that there's significant cross-pollination between applications, meaning that there's aspects of GRAIL's methylation technology that could be useful for noninvasive prenatal testing or genetic disease testing." (PFF ¶ 1142.2.)

- Dr. Febbo testified that "I see this kind of platform as having significant impact certainly in cancer testing. We'll see screening, which is what we're talking about. We'll also see these kind of signals helpful in cancer monitoring, but outside of cancer, we know that these signals could pick up on metabolic disease. So in the United States, obesity is a major challenge. There's . . . fatty changes in the liver, or NASH, causing NASH, an increasing healthcare concern, and . . . I don't know which application will go first, whether it's cardiovascular disease, metabolic disease, inflammatory disease[,] but I'm quite confident that as we look at these outliers, we'll see opportunities to build tests that serve as many [] patients as the screening test can serve." (PFF ¶ 1142.3.)

- Jay Flatley testified that the Board of Directors of Illumina determined that "we could take advantage of the data that's coming from the international expansion, human blood carries markers for all kinds of diseases, some of those yet to be discovered, but we do know that there are markers in the blood for neurologic diseases, such as Alzheimer's, markers for conditions like diabetes, and because GRAIL, again, has to be so focused on the Galleri test, they don't have the ability to move rapidly to develop these other tests, where in combination with Illumina, we could delegate resources to work on these other tests and bring follow-on, complementary tests to the market much more quickly." (PFF ¶ 1142.4.)

Here, again, Complaint Counsel did not put on any fact witnesses that undermined or even attempted to contradict this testimony. (PFF ¶ 1142.5.)

Respondents' experts corroborated the undisputed fact testimony that R&D efficiencies will arise from the reunion of Illumina and GRAIL. (PFF ¶ 1143.) As Dr. Carlton has explained: "simply put, you put some scientists who know one thing with scientists who know another thing, you put them together, and out of that collaboration comes new products,

new ideas, new ways of doing things that could not just lower costs but create – create new products . . . But my understanding is that the possibility for such types of R&D discoveries is a real one as a result of this transaction and that some of these possibilities include being able to do screening not just for cancer, but for neurodegenerative diseases, like Alzheimer's, fatty liver disease, cardiovascular disease. So all of these, it's my understanding, are possible benefits from this R&D collaboration". (PFF ¶ 1143.1.)

Evidence of R&D Efficiencies Is Unrefuted. [redacted]

Instead, Dr. Rothman states that the efficiency is not cognizable because Dr. Carlton did not assess the specific efficiencies that will be created or the cost of those efficiencies. (PFF ¶ 1144.2.) However, Dr. Rothman fails altogether to account for the undisputed *fact* testimony illustrated above; he simply ignores it. (PFF ¶ 1144.3.) Dr. Rothman also does not explain why understanding the exact costs of these efficiencies is necessary in order for them to be cognizable. (PFF ¶ 1144.4.) Moreover, Dr. Rothman admittedly only assessed the evidence in Dr. Carlton's pre-trial report and did not assess any other evidence, including affirmative testimony offered by Respondents' witnesses at trial. (PFF ¶ 1144.5 ("Q. GRAIL and Illumina's witnesses have not yet offered their direct testimony at trial, have they? We can agree on that? A. Yes. Q. Okay. You don't know what those witnesses are going to say under direct examination, by definition, right? A. That's correct.").) These flaws render Dr. Rothman's testimony useless and undeserving of any weight. *Barber v. United Airlines, Inc.*, 17 F. App'x 433, 437 (7th Cir. 2001) ("Because in formulating his opinion Dr. Hynes cherry-picked

the facts he considered to render an expert opinion, the district court correctly barred his testimony because such a selective use of facts fails to satisfy the scientific method and Daubert, and it thus fails to 'assist the trier of fact.'").[24]

Dr. Rothman also ignores Illumina's track record of generating R&D efficiency in a vertical transaction, unlike Dr. Carlton who recognized this track record of substantial R&D efficiencies. (PFF ¶ 1145.) The idea for Galleri came from another vertical transaction: Illumina's acquisition of Verinata, a company in the non-invasive prenatal testing business. (PFF ¶ 1145.2.) In the first hundred thousand women that received Illumina's noninvasive prenatal test, some unusual signals were identified. (PFF ¶ 1145.3.) Illumina formed a team and a program to evaluate early cancer detection signals and to follow up with patients and their prescribing physicians, which led to the discovery that the women with the unusual NIPT results had undiagnosed cancers. (PFF ¶ 1145.4.) It is that discovery that ultimately led Illumina to pursue development of an early cancer detection test and to found GRAIL. (PFF ¶ 1145.5.)[25]

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[24] [redacted] However, the firewall in the Open Offer is designed to protect against the sharing of third party confidential information and does not prevent Illumina and GRAIL from engaging in R&D activities. (PFF ¶ 1144.6 ("Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina").) Thus, it has no bearing on the R&D efficiencies shown at trial. (PFF ¶ 1144.6.)

[25] As Jay Flatley testified: "If you go back to the origin of GRAIL, one of the most important things that happened there was our acquisition of Verinata because it was that work that really was the light bulb moment that I think I described to you last time, about the actual failures in a number of cases of the NIPT test that caused us to realize that you can detect cancer by screening the blood. So those kinds of magical moments happen when you put people together that are working in related areas. So certainly some great opportunities would evolve there." (PFF ¶ 1145.6.)

Similarly, Rick Klausner, one of the founders of GRAIL, testified that: "So very soon after I had started at Illumina, I received either an e-mail or a phone call from a pathologist named

Verinata did not have the resources to research and develop an early cancer detection test on its own, and but for Illumina acquiring Verinata, no one would have developed an early cancer test research and development program despite the potential benefits of such a test. (PFF ¶ 1145.8) Illumina's track record of generating R&D efficiencies in connection with a vertical transaction corroborates the R&D efficiencies proven here. (PFF ¶ 1145.9 ("[W]e believe that there are R&D synergies between the two teams, so just like our team discovered the possibility to see cancer in blood because we were processing NIPT samples, we believe that it is going to be possible to develop a diagnostic test, a blood diagnostic test, to look for fatty liver disease, Alzheimer's, Parkinson's. But that requires the capabilities of the two companies to be brought together, and so we believe there are R&D synergies there.").

Courts have rejected merger challenges based on the presence of R&D efficiencies. *See, e.g., Deutsche Telekom*, 439 F. Supp. 3d at 209 (finding that the proposed merger's efficiencies outweighed the anticompetitive harms in part because the merger would

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Meredith Miller, who had been working at a company called Verinata that Illumina had at that time I think relatively recently acquired. And this was a company that was performing an LDT called NIPT for noninvasive prenatal testing, which is basically a liquid biopsy company I guess of sorts, but it's . . . not a company. It's a technology that measures the same type of circulating fragments of DNA that we now have been looking at for early cancer detection. And she had known of me. I think I had met her in the past. But told me a story that . . . she was the pathologist who was reading and signing off on the NIPT results and told me that she had collected a small number, less than 15 . . . of, as she described them, really weird results. And she didn't understand the results. She told me that she had basically concluded that the test didn't work, but to her great, you know, I think it's terrific that she was puzzled by and kept them. She wondered what they were. This was all happening very quickly because the scaleup of very long NIPT by multiple companies, including Verinata and then Illumina, had just gone very rapidly, hundreds of thousands of these tests, you know, quite extraordinary, and that was important, because of the hundred to thousand I don't remember the precise number that they had run, she only had these 12 to 15 that were, quote, this similar weird pattern. And she asked me if she could bring them by to show me these genomic readouts to see if I had any ideas about what was going on. So that was the framing of what was then going to change my mind about the possibility of a multicancer detection test." (PFF ¶ 1145.7.)

"reduce the cost and delay that T-Mobile would otherwise incur from building new towers for future network development", "accelerate mobile wireless carriers' provision of 5G" and "catalyze the earlier creation of new applications and services not currently possible in the 4G/LTE environment"); *AT&T I*, 310 F. Supp. 3d at 182–83, 191 n.17 (where the Court was "confident that defendants will achieve considerable efficiencies beyond those conceded by the Government" such as the "gains in innovation—particularly by way of a new programmatic advertising platform" before holding that the government failed to establish that the proposed merger violated Section 7 of the Clayton Act); *Great Lakes Chem. Corp.*, 528 F. Supp. at 94, 98 (finding that the procompetitive effects demonstrated the "absence of any lessening of competition", in part because "the acquisition will enhance critically needed research and development in the industry [as the acquiring company] is an acknowledged leader in research and development.").

D. The Reunion of Illumina and GRAIL Has Already Reduced GRAIL's Royalty Burden, Which Is a Benefit to Consumers.

The Transaction will also lead to significant efficiencies by reducing royalties that GRAIL was required to pay Illumina before the Transaction. (PFF ¶ 1146.) [redacted]

[redacted]

Royalty Savings Will Be Passed on to Consumers. The reduction of royalties resulting from the Transaction will be passed on to consumers in the form of lower prices. (PFF ¶ 1149.1.) [redacted] Dr. Aravanis testified that "[i]t is Illumina's plan to pass 100% of those efficiency savings on to payers of the test, so you know, physicians – or sorry – patients and, you know, other payers of the test." (PFF ¶ 1149.4.) [redacted]

[redacted]

Calculation of Royalty Efficiency. [redacted]

[redacted]

Royalty Efficiency Is Unrefuted. Here again, Complaint Counsel does not offer any fact witness testimony to the effect that the Transaction did not reduce GRAIL's royalty obligation or that the reduction would not benefit consumers. (PFF ¶ 1151.1.) Moreover, Complaint Counsel's experts do not opine on this efficiency in their reports. (PFF ¶ 1151.2.) There is no dispute that neither Dr. Rothman nor Dr. Navathe addresses this efficiency. [redacted]

[redacted]

Further, even if she had addressed it in her reports, her opinion that the royalty elimination could be achieved by contract, and that she does not believe there would be pass through to consumers, is contradicted by the undisputed factual testimony that the combined company will pass on the reduction to consumers [redacted]

Nothing in Dr. Scott Morton's reports or in the reports of Complaint Counsel's other experts changes the fact that cost savings are a well-recognized justification for a merger. *See, e.g.*, *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 148–49 (finding that the Government failed to prove that the merger would substantially lessen competition because the cost savings of "approximately 25 to 30 million dollars per year" due to the merger "will ultimately result in benefits to the consumers"); *Advocacy Org. for Patients & Providers v. Mercy Health Servs*., 987 F. Supp. 967, 975 (E.D. Mich. 1997) (denying plaintiff's request to block a merger because "an injunction would delay or foreclose the realization of cost savings [resulting from the merger] in the amount of $15 million annually to the people of Michigan"); *Carilion Health Sys.*, 717 F. Supp. at 846 (holding that the government failed to meet its burden to block a merger after finding that "Defendants' board of directors could be expected to help insure that savings realized from the affiliation will be passed on to consumers"); *AT&T I*, 310 F. Supp. 3d 161, 164,

173 (D.D.C. 2018) (where the government conceded that the "vertical merger would result in hundreds of millions of dollars in annual cost savings to AT&T's customers" and "reduce the 'bargaining friction' inherent in the arm's-length affiliate negotiations . . . between traditional programmers and distributors" before the Court approved the merger).

E. The Reunification of Illumina and GRAIL Will Result in Elimination of Double Marginalization.

Elimination of Double Marginalization ("EDM") is a well-documented efficiency from a vertical transaction that occurs when an upstream firm acquires a downstream firm to which it supplies inputs. (PFF ¶ 1152.) Complaint Counsel's own expert acknowledges that EDM is a benefit that can often arise from vertical mergers. [redacted][26]

As explained by Dr. Carlton: "EDM benefits arise when an upstream firm with market power acquires a downstream firm with market power to which it supplies inputs. 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

[26] 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* Vertical Merger Guidelines at 2 ("Vertical mergers, however, also raise distinct considerations, which these Guidelines address. For example, vertical mergers often benefit consumers through the elimination of double marginalization, which tends to lessen the risks of competitive harm."); 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.")).

firms merge, there is a single firm with the marginal costs of what was formerly the upstream firm and which faces the same demand curve as the former downstream firm. Thus, the margin of the upstream firm is internalized and there is an effective reduction in the marginal cost of producing the downstream product; put differently, the merger leads a profit maximizing firm to eliminate the upstream margin from its downstream pricing decision and to reduce the price of the downstream good." (PFF ¶ 1152.2.)

Conditions for EDM Are Present Here. The conditions for elimination of double marginalization are present in this Transaction. (PFF ¶ 1153.) Before the Transaction closed, Illumina charged a margin to GRAIL on sales of its NGS products, and GRAIL projected a margin on its products. (PFF ¶ 1153.1.) Dr. Carlton testified:

> "If you look at the data, if you look, for example, at the deal model, what is Illumina projecting is going to be happening, say, in -- you know, in the future, there's double-marginalization, period. That's what the evidence is. What about now? Yes. There is just no question, double-marginalization is going on now, double-marginalization in the sense that price that is being charged to GRAIL is not marginal cost. That's just crystal clear in the data. So they haven't gotten rid of double-marginalization. As far as I can tell, Illumina has never gotten rid of double-marginalization with GRAIL or any of these third-party MCED developers. There's always a margin. But just look at the deal model. That is really excellent evidence. The deal model is telling you, absent the merger, here are Illumina's projections. No question, crystal clear, there is a margin that Illumina is charging to GRAIL."

(PFF ¶ 1153.2)

Calculation of EDM Efficiency. [redacted]

[redacted]

[redacted]

EDM Efficiency Unrefuted. Complaint Counsel does not present any factual testimony or other evidence suggesting that there were not two margins prior to the Transaction or that the elimination of double marginalization will not be achieved. (PFF ¶ 1155.1.) Rather, Complaint Counsel's economic expert argues that EDM will not be achieved here because Respondents could have achieved these procompetitive benefits before the Transaction, given the complex contracts that already exist between the parties, and chose not to do so. (PFF ¶ 1155.2.) This assertion, however, follows from Dr. Scott Morton's unsupported assumption that EDM can easily be eliminated by contract, and hence, if double marginalization is not achieved by contract, then the current pricing structure that exists must be efficient and would not be

improved upon post-merger. (PFF ¶ 1155.3.) But this reasoning, if true, would eliminate the rationale for every vertical merger, as all EDM benefits (as well as any other efficiencies) could be achieved by contract under Dr. Scott Morton's theory. (PFF ¶ 1155.4.) In fact, Dr. Scott Morton's assumption flies in the face of longstanding economic literature, case law, and the Vertical Merger Guidelines. *See e.g.*, *AT&T I*, 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). Even if EDM could be achieved by contract in certain circumstances, the undisputed evidence shows that it was not and would not have been eliminated here. (PFF ¶ 1155.5 ("Well, you can say anything can happen. The fact of the matter is it hasn't happened. The reason why the evidence in this case is so strong, I think, to refute what Dr. Scott Morton is saying, is because it's obvious that, absent the merger, Illumina will charge GRAIL and does charge GRAIL and expects to charge GRAIL a price above its marginal cost, period. It's crystal clear from the documents.").)

Contrary to Complaint Counsel's present view, the elimination of double marginalization is a well-accepted efficiency of vertical integrations, as numerous courts have recognized. *See*, *e.g.*, *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 465 (7th Cir. 2020) (interpreting *Port Dock & Stone Corp. v. Oldcastle Northeast, Inc.*, 507 F.3d 117 (2d Cir. 2007)—which affirmed the district court's dismissal of the plaintiff's complaint against a vertical integration—as an illustration of elimination of double marginalization); *Alberta Gas Chems Ltd. v. E.I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1247 (3d Cir. 1987) ("Because of post-merger efficiencies allowing [a firm] to purchase the acquiring company's output at a better price than in the marketplace, the acquired company's purchasing costs would fall—a procompetitive benefit capable of being passed on via lower prices for its products. Thus, in this scenario, post-

merger self-dealing could result in efficiencies reflected in lower prices to the ultimate consumer") (holding that the plaintiff failed to present evidence of antitrust injury); *U.S. v. AT&T Inc.*, 310 F. Supp. 3d 161, 193, 197 (2018) ("[T]he Government concedes that this case implicates one 'standard benefit' associated with vertical mergers: the elimination of double marginalization ('EDM')") (finding that the Government failed to prove that the merger would substantially lessen competition).

F. The Reunion of Illumina and GRAIL Will Lead to Additional Efficiencies

The Transaction will not just save lives, accelerate market access, generate R&D efficiencies, reduce GRAIL's royalty burden and eliminate double marginalization. (PFF ¶ 1156.) The reunion of Illumina and GRAIL will also (1) lead to supply chain and operational efficiencies and (2) accelerate the international expansion of Galleri. (PFF ¶ 1156.)

1. The Reunion of Illumina and GRAIL Will Lead to Supply Chain and Operational Efficiencies.

Reuniting Illumina and GRAIL will allow them to achieve significant supply chain and operational efficiencies. (PFF ¶ 1157.) The evidence of this is entirely one-sided, fully favoring Respondents. (PFF ¶ 1158.) Complaint Counsel presented no fact witness or other evidence rebutting the testimony of Respondents' fact witnesses on these efficiencies. (PFF ¶ 1157.)

Supply Chain Efficiencies. Illumina has been operating in the NGS space for over a decade. (PFF ¶ 1159.) During that time, Illumina has developed relationships with suppliers from whom it purchases in large volumes. (PFF ¶ 1159 ("That supply chain is very deep. It goes all the way back to primary formulations of products.").) These relationships allow Illumina to purchase inputs at a significant discount. (PFF ¶ 1160.) By contrast, GRAIL

is a young company that has only one product on the market with very limited sales. (PFF ¶ 1161.)

It is well recognized that purchasing in large volume can generate cost saving to the supplier and that can lead to volume discounts. (PFF ¶ 1162.) The reunion of Illumina and GRAIL will allow GRAIL to benefit from Illumina's prices and relationships in areas of common products. (PFF ¶ 1162.1.) Multiple witnesses addressed these efficiencies (PFF ¶ 1162.1):

- Francis deSouza, CEO and President of Illumina, testified that: "We have supply contracts with a large number of suppliers, and we purchase a number of raw materials in -- that GRAIL also uses in much higher quantities than GRAIL does. So what that means is we are able to get deeper discounts for those raw materials than GRAIL is able to do. And so by consolidating purchasing for these materials between GRAIL and Illumina, GRAIL would enjoy bigger discounts than it gets today for a lot of the materials that it has. In addition, we have conducted -- just because we have a lot more experience and a bigger team, we have been able to identify vendors that provide superior cost performance points across the products that we buy, and because we have been able to do that, you know, more extensively than GRAIL has so far, there are areas where we've identified vendors that offer superior cost performance than the vendors that GRAIL would use, and so they're able to take advantage of those capabilities as well. And then as a global company, we're able to enjoy the benefits of leveraging a supply chain that is global, and so, again, that gives us access to a superior cost performance supply chain than GRAIL would have on its own." (PFF ¶ 1162.2.)

- Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "[D]uring the due diligence process, we identified common suppliers for core components of the Galleri assay. Again, these are common to components that Illumina purchases today at a very large scale, a very large volume. The cost reductions associated with volume that Illumina benefits from could be shared with GRAIL as part of an integrated company. Therefore, the cost of goods for the Galleri test would decrease." (PFF ¶ 1162.3.)

- Jay Flatley, Chairman of the Board of Illumina at the time the Transaction was entered into, testified that the Board of Directors of Illumina determined that "Illumina and GRAIL both buy significant amounts of reagents and chemicals from third parties. That supply chain is very deep. It goes all the way back to primary formulations of products. Together, we'd have the ability to combine volumes and, therefore, reduce the prices that we paid for those reagents, because many of the reagents are common in the kind of tests that GRAIL runs versus some of the tests that Illumina runs. We also would have the ability to have increased purchasing

power. So at times where supplies are constrained, like they were during the COVID era -- continuing, in fact -- we would have more purchasing power as a combined entity than either of us would as individual entities." (PFF ¶ 1162.4.)

- Hans Bishop, CEO of GRAIL, testified that "As part of Illumina, I think we'll scale faster, and scale brings cost benefits." (PFF ¶ 1162.5.)

Complaint Counsel did nothing on cross examination to undermine this testimony; nor did it offer any fact witness testimony to the contrary. (PFF ¶ 1162.6.) Evidence of this efficiency is therefore unrefuted. (PFF ¶ 1162.7.)

Lab Operation Efficiencies. Illumina also has significant experience managing laboratories that operate NGS tests at scale. (PFF ¶ 1163.) As Francis deSouza explained, Illumina has been operating laboratories at scale "for well over a decade now. We have labs in the U.S. but also outside the U.S. . . Our labs have already been delivering tests in the millions of tests a year to consumers and have been doing that for a while." (PFF ¶ 1163.1) Illumina operates genomic tests for cancer therapy selection, genetic disease diagnosis and other uses. (PFF ¶ 1163.2.) Illumina has also optimized its workflow from a cost and safety perspective. (PFF ¶ 1163.3 ("Illumina has developed automation capabilities to automate assays and reduce cost. It's also developed the capabilities to dynamically staff large sequencing operations and by doing so reducing labor costs associated with that. It's also developed the ability to efficiently use real estate and laboratories.").) GRAIL, in contrast, only has one laboratory and limited experience operating that lab. (PFF ¶ 1164.)

Combining Illumina and GRAIL will allow GRAIL to benefit from Illumina's lab operations capabilities. (PFF ¶ 1165.) Undisputed fact testimony established this efficiency (PFF ¶ 1165.1):

- Francis deSouza, CEO and President of Illumina, testified that: "[W]e already have the lab facilities, the real estate facilities. We already have the equipment in the labs. We already have the personnel that are trained to run genomics, and it requires a certain level of sophistication to run a genomics pipeline. In addition to that, we have

optimized the work flows associated with running a genomics lab, things like that sample accessioning, how do you bring in, you know, from a logistics perspective but then also, on the facility itself, how do you unpack a lot of samples? How do you maintain a chain of custody with integrity as a sample comes in to your position all the way, you know, until you return data? We have also been able to optimize the work flow end to end from a safety perspective, from a supply chain -- sorry, chain of custody perspective, and from a cost perspective. We've also developed the custom automation tools it takes to run a highly automated lab. We've also developed the software pipeline it takes to analyze the data in a very high throughput way coming off those samples. So, you know, all of those operational capabilities are benefits that GRAIL will enjoy, and it will take GRAIL years to develop that capability themselves." (PFF ¶ 1165.2.)

- Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "So Illumina has developed automation capabilities to automate assays and reduce cost. It's also developed the capabilities to dynamically staff large sequencing operations and by doing so reducing labor costs associated with that. It's also developed the ability to efficiently use real estate and laboratories. We believe that will lower the facilities costs that GRAIL will incur, and those, again, costs can be passed on to people purchasing the test." (PFF ¶ 1165.3.)

- Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "Well, both companies run laboratories. GRAIL has one. Illumina has several of these around the world. And to the extent that we could integrate those lab operations, we would have much more consistent protocols, much more consistent software, both on the -- how we bring samples into the laboratory and how we control the samples and build the databases around the sample information, but also on the reporting side, as well as the what are called lab information management systems, which control sample processing through the overall laboratory. Separate, those systems would be very divergent, and patients would get different types of reports, and the sample control and the data sets would be independent. In a combined company, we would have the ability to integrate that in a very important way and leverage the data across multiple tests for a given patient and have much more unified software structures and reporting." (PFF ¶ 1165.4.)

- Hans Bishop, CEO of GRAIL testified that "Illumina has established operations and the relevant teams of experts and laboratories in certain instances in many countries around the world" that will help GRAIL scale. (PFF ¶ 1165.5.)

Here again, Complaint Counsel failed to undermine this testimony in cross, and it offered no fact witness testimony to the contrary. (PFF ¶ 1165.6.)

Calculation of Supply Chain and Operational Efficiencies. Illumina has quantified the monetary cost savings from supply chain and operational efficiencies as at least

$140M over a 10-year period. (PFF ¶ 1166.) Complaint Counsel offered no evidence to the contrary. (PFF ¶ 1166.)

Supply Chain and Operational Efficiencies Unrefuted. Complaint Counsel does not dispute that supply chain and operational efficiencies may arise from a vertical transaction. (PFF ¶ 1167.1.) Nor did it call any witness to dispute the testimony from Illumina and GRAIL witnesses. (PFF ¶ 1167.2.) [redacted] However, Respondents do not depend on either Dr. Carlton or the document he cited for this efficiency. (PFF ¶ 1167.4.) Dr. Rothman's opinion merely assessed whether the efficiency was verifiable based on a single spreadsheet and did not independently assess any other evidence regarding this efficiency, including the direct testimony regarding these efficiencies outlined above. (PFF ¶ 1167.5.)

Courts have found cost savings arising from similar supply chain and operational efficiencies sufficient to justify mergers. *See*, *e.g.*, *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121, 147 (E.D.N.Y. 1997) (approving the merger because "[a]mong these merger-related savings are: a reduction in personnel in various departments of both hospitals . . .; some reduction in the cost of clinical laboratory services and medical supplies; claims recovery costs and utilities; laundry costs; in-house consulting services; and computer and information services."); *FTC v. Lab'y Corp. of Am.*, No. SACV 10-1873 AG MLGX, 2011 WL 3100372, at *10-11 (C.D. Ca. 2011) (denying the FTC's request for a preliminary injunction enjoining the merger) ("LabCorp presented evidence that the transaction will result in over $22 million annually in merger-specific efficiencies resulting from consolidating redundant facilities and

employees and taking advantage of LabCorp's lower supply costs"); *FTC v. Butterworth*, 946 F. Supp. 1285, 1301 (W.D. Mich. 1996) (hospitals successfully rebutted the government's prima facie case because of evidence that "the proposed merger would result in significant efficiencies, in the form of capital expenditure avoidance and operating efficiencies, totaling in excess of $100 million" which "is, by any account, a substantial amount"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 209 (S.D.N.Y. 2020) (finding that the proposed merger's efficiencies outweighed the anticompetitive harms as the proposed merger would "save $4.2 billion in operating costs per year" and create savings "from streamlined advertising, the closing of 3,000 redundant retail stores, and reducing the costs of billing and other professional 'back office' services").

2. The Reunion of Illumina and GRAIL Will Accelerate the International Expansion of Galleri.

The Transaction will accelerate the international expansion of Galleri because it will put Illumina in a position to leverage its significant international resources for GRAIL. (PFF ¶ 1168.) Complaint Counsel did not present any fact witnesses or evidence to rebut the testimony of Respondents' fact witnesses on this efficiency. (PFF ¶ 1168.1.)

Illumina's International Presence and Capabilities. Illumina has a strong international presence with platforms and/or tests registered in over 140 countries around the world. (PFF ¶ 1168.2.) As Mr. deSouza explained, "[Illumina has] a strong international presence. In fact, more than half of Illumina's revenue today comes from outside the U.S., and so the countries outside the U.S. represent the majority of Illumina's business today . . . Today, we've placed products in over 140 countries around the world. We have clear products in dozens of countries around the world. We have partners, we have sales teams, we have in-market surveillance teams to make sure that we are quick to recognize if there's any issue our

customers are having and be able to respond. We're able to market into those countries". (PFF ¶ 1168.3.) Illumina has significant experience working with foreign regulators and payors and with obtaining regulatory approvals. (PFF ¶ 1168.4.)

GRAIL's Lack of International Reach. By contrast, GRAIL has no presence outside of the United States and the United Kingdom. (PFF ¶ 1169.) Due to its limited international presence, GRAIL has not made plans to expand internationally in the near future and in fact has been unable to accept offers to provide its Galleri product to other countries due to a lack of capacity. (PFF ¶ 1169.1 ("Q. And what ability do you have to develop international sales today? A. Yeah . . . we have enough people to talk to people but not enough to actually do anything, so we've often in a position of people reaching out to do things and us, you know, being polite and having to say we just can't take it on right now.").)

The Transaction Will Accelerate International Expansion. Through the proposed transaction, Illumina will dramatically increase GRAIL's ability to access international markets and to achieve regulatory and payor approvals outside the United States. (PFF ¶ 1170.) The fact testimony on this score was undisputed (PFF ¶ 1170.1):

- Francis deSouza, CEO and President of Illumina, testified that: "I do know what impact international expansion will have on the GRAIL test. By accessing larger sample sets, by accessing the genomes from more patients or more consumers around the world, the GRAIL test will become more and more accurate, and this is a test that's based on a learning algorithm, and so accessing larger sample sets will improve the GRAIL test for people here in the U.S. In addition, accessing more diverse genomes than are available in the U.S., which you will get access to as you enter, you know, continents like Africa or Asia or Latin America, or even in the European Union, accessing the more diverse – the bigger biodiversity associated with those genomes will improve the test for people here in the U.S. This is a special issue in genomics because the cohorts that are used here in the U.S. to develop genomic tests are predominantly Caucasian cohorts. What that means is if you are an African-American person in the U.S. or a number of other minorities, the genomic tests just simply aren't as good for you as they are for Caucasians, and that's just a health inequity we're dealing with in the U.S. that we will be able to address more fully as

we expand the cohorts to include cohorts from Africa and from Asia." (PFF ¶ 1170.2.)

- Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "The basis of the determination is, number one, our plans for making the Galleri test available in the many countries around the world that we operate, that GRAIL does not operate today, so that's our basis of the determination, that the test will be available worldwide, much faster than GRAIL could given that it has no operations in those countries. With offering that test in many countries in the world, that will generate a significant amount of testing data. We know that that testing data will be useful in payer discussions around the questions they'll have around clinical utility. We also know that that data will be useful in creating future versions of the Galleri test. We also know that that data will be useful in discussions with the FDA around FDA approval." (PFF ¶ 1170.3.)

- Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "[g]oing into international markets is complicated. It requires often the setup of subsidiaries and legal entities. It requires hiring and employees and, therefore, setting up tax structures and all of the structures around how stock options get issued to employees. It's quite a complicated and expensive process to set up subsidiaries in countries around the world. Illumina has this in place in all of the major countries of the world, and GRAIL would have the ability to leverage that very directly even if the sales force were separate, which in some cases it would be. In some cases where we have distributors, distributors might sell both products directly to the customer, but the infrastructure that Illumina has in place would dramatically accelerate GRAIL's ability to bring Galleri to other markets of the world and to do that quite quickly." (PFF ¶ 1170.4.)

- Hans Bishop, CEO of GRAIL, testified that "first of all, selling Galleri more broadly, you know, outside the United States will have a series of country-specific regulatory approvals. We don't have a team today that has any experience of that. Illumina already has those people. Secondly, to supply a particular country requires you to have a business and capabilities in that country. And outside of the U.K., we don't have any offices around the world. Illumina has many. Thirdly, the financial resources and engineering expertise to build the infrastructure that's needed on top of what they already have is a much easier step than as a standalone company today with a very limited footprint outside the U.S." (PFF ¶ 1170.5.)

- Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "GRAIL has been focused on the U.S. domestic market. We do have a study in the U.K. with the NHS. Other than that, our long-range plan for the next ten years, you know, really ignores anything international. We don't have any international operations other than, you know, 10-20 people in the U.K. to facilitate the NHS study. And you know, you compare that to, as I said, a multinational, billion-dollar-plus company with multiple products, locations all over the globe, and it's pretty obvious to me that they could accelerate us internationally if they have the infrastructure already." (PFF ¶ 1170.6.)

International expansion will have a positive effect on Galleri's operations in the United States, because it will allow Galleri to gather data from more patients in less time and will allow Galleri to ensure a more representative and diverse dataset that can be used to accelerate clinical validation for GRAIL's PMA submission as well as provide clinical utility evidence for payor adoption and reimbursement in the United States. (PFF ¶ 1171.)

International acceleration will also help improve the Galleri test. (PFF ¶ 1172.) As Francis deSouza testified, "by accessing a bigger market, you get a better test because the algorithms continue to get refined, and you get better and better accuracy in the test the more samples you run. This is especially true if the samples are genomically diverse. . . . the benefit you get from running this test globally is not just driven by the fact that you are running more tests and that gives you more accurate performance. Running more tests in regions where there's high genomic biodiversity, you know, in Africa, for example, in Asia, for example, or even just extending from the UK into the rest of the European Union, or going into Latin America, gives you a more diverse set of genomes. That gives you a better test. And so long term, global expansion is important to the success of the MCED test in at least those two dimensions." (PFF ¶ 1173.)

International Acceleration Efficiency Unrefuted. Complaint Counsel did not call any fact witness who undermined the testimony from Illumina and GRAIL witnesses. (PFF ¶ 1173.1.) [redacted] Thus, there is no actual dispute that the Transaction will accelerate international adoption of Galleri. (PFF ¶ 1173.3.)

Courts have found acceleration of international expansion to be sufficient to justify a merger. *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 98 (N.D. Ill. 1981) (denying the FTC's request for injunction against the proposed acquisition in part because "the acquisition will serve the national interest by promoting foreign trade. . . . Because Great Lakes plans to increase bromine-related sales abroad, the proposed transaction will result in increased exports and will benefit the nation's balance of payments and the economy as a whole. In this regard, courts have recognized that the "stimulation of additional international . . . activity is procompetitive and beneficial.'") (citations omitted). This Court should come to a similar conclusion.

G. The Benefits of the Transaction Are Merger Specific.

Each of the efficiencies arising from the Transaction is merger specific because each was not, and could not have been, achieved but for the Transaction.

Acceleration Efficiencies Are Merger Specific. The acceleration efficiencies are merger specific because it would not be possible to achieve these efficiencies without the Transaction. As numerous Illumina and GRAIL fact witnesses testified, Illumina's capabilities with regulatory approval, market access and international expansion are a product of years of work and cannot be easily replicated. (PFF ¶ 1175 ("[O]ur ability to scale the business is limited if we are doing this on our own. It will take a long time. And if we're part of Illumina, I firmly believe that that time will be greatly accelerated, and so our ability to achieve our aspiration will not only be accelerated but actually, you know, fortified by being part of a company with the magnitude and the capabilities of Illumina").)

Fact witnesses with personal knowledge also testified that GRAIL could not achieve these efficiencies by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up

to speed on the specific needs in a new area such as screening. (PFF ¶ 1175.2.1, PFF ¶ 1175.2.2 ("you build institutional capability over time internally that might not be the subject-matter expertise of those consultants, because, again, consultants are teams that come and go, so they do not have that institutional expertise. . . . [T]hat's really the main reason why . . . a group of consultants cannot do the work with companies. And our, again, experience when we needed to use consultants even for strategy work, it has been a steep learning curve in many cases when it comes to the applications or clinical applications we're dealing with."); [redacted]

Illumina and GRAIL witnesses testified that they could not contract for these efficiencies if they were separate entities because Illumina does not provide such services to any third-party entities and doing so would require GRAIL to share its confidential information with Illumina. (PFF ¶ 1175.3 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't . . . otherwise share."); [redacted]

The fact testimony is consistent with unrefuted expert testimony. (PFF ¶ 1175.4.) As Dr. Carlton explained, the acceleration efficiencies are merger specific because:

- Illumina Does Not Offer Regulatory or Market Access Assistance to Third Parties. "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to GRAIL to help it get FDA approval or payer approval." (PFF ¶ 1175.4.1.)

- GRAIL Would Not Share Confidential Information. "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through." (PFF ¶ 1175.4.2.)

- Illumina and GRAIL Testimony Supports Merger Specificity. "[B]oth Mr. deSouza and Bishop have told me that this acceleration won't be achieved by, you know, just hiring consultants or outside staff." (PFF ¶ 1175.4.3.)

Complaint Counsel argued the Transaction's acceleration benefits are not merger specific, but it presented no evidence to support the assertion. (PFF ¶ 1175.5.)

R&D Efficiencies Are Merger Specific. Similarly, the R&D efficiencies described above are merger specific because they could not be achieved without the Transaction. (PFF ¶ 1176.) Every single fact witness to address the issue testified—without exception—that

it would take GRAIL *years* to develop the R&D capabilities Illumina has today. (PFF ¶ 1176.1.) Illumina and GRAIL could not achieve the efficiencies at issue by contract because Illumina does not offer such services to third parties and GRAIL would be unwilling to collaborate on R&D projects with a third party because doing so would require GRAIL to share its "secret sauce" with Illumina. (PFF ¶ 1176.2 ("without understanding in depth the specifics of the sequencing that's performed, the specifics of the bioinformatics that goes from that sequencing and pulls out the methylation patterns that -- and then the machine-learning that's used to identify that cancer detection signal, to identify that tissue of origin of signal, without deeply understanding that, it's almost impossible for our scientists, who know the technology better than any other company, to realize efficiencies. So you have to get to that deep, fundamental understanding and exchange in order to realize the full benefit of coming together and the full efficiencies.");

Here again, the undisputed fact witness testimony is consistent with Dr. Carlton's testimony regarding why the acceleration efficiencies are merger specific (PFF ¶ 1176.3):

- Illumina and GRAIL Would Not Share Confidential Information With Third Parties. "[P]robably the simplest reason is it's very well established in the economics literature, it's very hard to transact in information, and those are exactly the circumstances when vertical integration makes sense. That aligns exactly with what I told you earlier about how GRAIL is worried about proprietary information." (PFF ¶ 1176.3.1.)

- Illumina Does Not Provide R&D Consulting Services. "Illumina does not provide R&D consulting to its clinical customers. As I've told you, GRAIL has explained that they will not share proprietary information in an arm's length negotiation with Illumina, in particular proprietary information about its machine-learning algorithm, and it is not the case, based on my understanding of the evidence, that there's any possibility that these R&D efficiencies could be achieved by contract, by hiring outside -- outside people." (PFF ¶ 1176.3.2.)

Complaint Counsel presented no fact evidence that suggests that the acceleration benefits are not merger specific, and the attempts by its economic experts (who have no experience as a basis to opine on the reasonableness of such efficiencies) to dismiss such evidence by saying the gains could theoretically be attained by contract should be dismissed as unsubstantiated speculation. (PFF ¶ 1176.4.)

EDM, Elimination of the Royalty and Supply Chain and Operational Efficiencies Are Merger Specific. The remaining cost-saving efficiencies are merger specific, because they too have not occurred, and would not occur, absent the Transaction. (PFF ¶ 1177.) [redacted]

As explained, both Illumina and GRAIL have an incentive to eliminate double marginalization. (PFF ¶ 1177.2.) If it were feasible to achieve EDM through contract, Illumina and GRAIL would have already done so pre-merger. (PFF ¶ 1177.3.) The fact that they did not do so is proof that there is no evidentiary basis to speculate that this efficiency would not be achievable by contract absent the merger. (PFF ¶ 1177.4.) The same is true of the elimination of the royalty and the supply chain and operational efficiencies. (PFF ¶ 1177.5 ("[T]he evidence is that premerger, the royalty was not removed. . . [redacted]; PFF

¶ 1177.5 ("I'm not aware of any, you know, contracting, nor does she cite any, that's been done to achieve those efficiencies").) Dr. Scott Morton provided no reason why the parties would not have achieved these efficiencies through contract if it were feasible to do so. (PFF ¶ 1177.6.)

H. The Contentions of Complaint Counsel's Experts About Efficiencies are Baseless.

Complaint Counsel's only real response to the overwhelming and undisputed evidence that the Transaction will generate sizeable efficiencies is to fall back on its experts' assertions that the efficiencies are unsubstantiated. (PFF ¶ 1178.) That is no answer for multiple reasons.

First, whether an efficiency is substantiated is a question for the Court; it is not an appropriate subject of expert testimony. *FTC v. Simple Health Plans LLC*, No. 18-CV-62593-, at *21–22 (S.D. Fla. Mar. 3, 2021) (excluding the expert's testimony because the expert was "opining about the sufficiency of [Plaintiff's] evidence" and thus impermissibly instructed the factfinder "about how to weigh the evidence") (quotations omitted); *In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61, 64 (S.D.N.Y. 2001) ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law."); *Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009) ("[A]n expert may never render conclusions of law.") (citations omitted); *United States v. Thanh Quoc Hoang*, 891 F. Supp. 2d 1355, 1361-62 (M.D. Ga. 2012) ("[An expert] cannot offer testimony about the legal implications of evidence.").

Second, the efficiencies are supported by fact testimony that Complaint Counsel's experts, for the most part, did not even consider. Their opinions amount to a critique of the opinions of Respondents' experts, whose opinions represent only a portion of Respondents' case.

Third, Complaint Counsel's experts arrive at their conclusions by weighing the evidence, crediting the testimony that fit Complaint Counsel's thesis and dismissing the evidence that did not—again usurping the role of the Court. *United States v. Adams*, 271 F.3d 1236, 1245

(10th Cir. 2001) ("The credibility of witnesses is generally not an appropriate subject for expert testimony."); *Ellis v. Hobbs Police Dept.*, 472 F. Supp. 3d 1087, 1096 (D.N.M. 2020) (same); PFF ¶ 1178.1 (Scott Morton stating that she "weighed [witness statements] according to the information they had, the role they play in the company and the type of competition in which they are engaged.")).

Any continued claim that the efficiencies of the transaction were unsubstantiated is contradicted by the sworn testimony of no less than ten trial witnesses: Francis deSouza (President and CEO of Illumina), Dr. Alex Aravanis (Chief Technology Officer of Illumina and former head of R&D at GRAIL), Dr. Phil Febbo (Chief Medical Officer of Illumina), Ammar Qadan (Vice President and Global Head of Market Access at Illumina), Jay Flatley (former CEO and Chairman of the Illumina Board of Directors at the time of the Transaction), Hans Bishop (CEO of GRAIL), Dr. Joshua Ofman (Chief Medical Officer of GRAIL), Aaron Freidin (Senior Vice President of Finance at GRAIL), Chris Della Porta (Director, Growth Strategy, at GRAIL) and Dr. Arash Jamshidi (Senior Vice President of Data Sciences at GRAIL). (PFF ¶ 1179.) It is also counter to the independent judgments of Illumina Board members knowledgeable about the industry: Dr. Frances Arnold (Director, Chairperson of Science and Technology and Nominating); Francis deSouza (Director, CEO), Caroline Dorsa (Director, Chair of Audit Committee), Dr. Robert Epstein (Director, Chair of Governance Committee), Jay Flatley (Chairman and former CEO), Dr. Scott Gottlieb (Director), Dr. Gary Guthart (Director, Chair of Compensation Committee), Philip Schiller (Director), Susan Siegel (Director) and John Thompson (Lead Independent Director). (PFF ¶ 1179.) Complaint Counsel offered nothing in response.

* * *

In sum, the Transaction will generate numerous efficiencies, including accelerating the adoption of Galleri, streamlining the supply chain, streamlining operations, accelerating international expansion, generating R&D efficiencies and, most importantly, saving lives. This evidence justifies allowing the Transaction, easily offsetting any alleged harm.

V. COMPLAINT COUNSEL'S CHALLENGE TO THE TRANSACTION VIOLATES THE U.S. CONSTITUTION.

Complaint Counsel's challenge to the Transaction should be rejected because it violates Article II and the Due Process and Equal Protection Clauses of the U.S. Constitution. The FTC's case violates Article II, because FTC ALJs are afforded dual-layer protection from presidential review. It violates the Due Process Clause, because the FTC is acting simultaneously as prosecutor, judge, and jury. And it violates the Equal Protection Clause, because it irrationally deprives Respondents of the structural and procedural protections they would possess in a challenge brought by the U.S. Department of Justice's Antitrust Division ("DOJ").

A. The FTC Violates Article II.

In their challenge to Illumina's reunion with GRAIL, Complaint Counsel and the Commission have impinged upon the executive power vested in the President of the United States in violation of Article II of the U.S. Constitution.

Article II of the U.S. Constitution vests "[t]he executive Power . . . in a President of the United States of America", who must "take care that the laws be faithfully executed". U.S. Const. art II, § 1, cl. 1, § 3. In light of "[t]he impossibility that one man should be able to perform all the great business of the State", the Constitution provides for executive officers to "assist the supreme Magistrate in discharging the duties of his trust." 30 Writings of George Washington 334 (John C. Fitzpatrick ed., 1939).

Since 1789, the Constitution has been understood to empower the President to keep these officers accountable by removing them from office if necessary. *See generally Myers v. United States*, 272 U.S. 52 (1926). The Supreme Court has recognized only two exceptions to the President's unrestricted removal power. In *Humphrey's Executor v. United States*, 295 U.S. 602 (1935), the Court held that Congress can, under certain circumstances, create independent agencies run by principal officers, whom the President may not remove at will but only for good cause. Likewise, in *United States v. Perkins*, 116 U.S. 483 (1886), and *Morrison v. Olson*, 487 U.S. 654 (1988), the Court sustained similar restrictions on the power of principal executive officers—themselves responsible to the President—to remove their own inferiors.

In *Free Enterprise Fund v. Public Co. Accounting Oversight Board*, the Court considered "whether these separate layers of protection may be combined"—that is, whether the President may "be restricted in his ability to remove a principal officer, who is in turn restricted in his ability to remove an inferior officer, even though that inferior officer determines the policy and enforces the laws of the United States". 561 U.S. 477, 483-84 (2010). The Court held that "such multilevel protection from removal is contrary to Article II's vesting of the executive power in the President". *Id.* at 484. The President cannot "'take Care that the Laws be faithfully executed' if he cannot oversee the faithfulness of the officers who execute them." *Id.*

Here, Complaint Counsel's challenge runs afoul of Article II, because it seeks to undo the Transaction in a proceeding in which the President cannot "take Care that the Laws be faithfully executed", as he cannot adequately oversee the faithfulness of the officers who execute them. There is no question that FTC ALJs enjoy two layers of protection from the President. *See In re Otto Bock HealthCare N. Am., Inc.*, No. 9378, 2019 WL 5957363, at *49 (FTC Nov. 1, 2019) (acknowledging that FTC ALJs enjoy dual-layer protection from presidential review) (PFF

¶ 1181.) Like the Public Company Accounting Oversight Board ("PCAOB") members that the Court considered in *Free Enterprise Fund*, FTC ALJs may be removed only "for good cause established and determined by" someone other than the President, namely the Merit Systems Protection Board ("MSPB"). 5 U.S.C. § 7521(a). And like the SEC Commissioners who wielded limited removal power in *Free Enterprise Fund*, MSPB members may be removed by the President only for "inefficiency, neglect of duty, or malfeasance in office." 15 U.S.C. § 41.. "Neither the President, nor anyone directly responsible to him, nor even an officer whose conduct he may review only for good cause, has full control over" FTC ALJs. *Free Enter. Fund*, 561 U.S. at 496. These removal procedures are therefore "contrary to Article II's vesting of the executive power in the President." *Id.*

In prior challenges under Article II, the FTC has argued that the dual-level of protection afforded to FTC ALJs is of no constitutional moment because they are not "Officers of the United States". *See In re LabMD, Inc.*, No. 9357, Compl. Counsel's Opp'n to Resp't's Mot. to Amend Affirmative Defenses and to Dismiss this Proceeding 2-3 n.2-3 (Jul. 24, 2015). Following the Supreme Court's decision in *Lucia v. SEC*, 138 S. Ct. 2044 (2018), however, that argument is untenable. In *Lucia*, the Court held that SEC ALJs are "Officers of the United States". 138 S. Ct. at 2053–54. And there is no constitutionally significant difference between FTC ALJs and the SEC ALJs held to be "Officers of the United States" in *Lucia*. *Id.* Both may be "appoint[ed]" by their respective Commissions. 5 U.S.C. § 3105. Both "exercis[e] significant authority pursuant to the laws of the United States" by exercising the authority needed to ensure fair and orderly adversarial hearings. *Freytag v. Comm'r of Internal Rev.*, 501 U.S. 868, 881 (1991) (quoting *Buckley v. Valeo,* 424 U.S. 1, 126 (1976)). Both "take testimony", "conduct trials", "administer oaths, rule on motions, and generally 'regulat[e] the course of' a

hearing, as well as the conduct of parties and counsel". *Lucia*, 138 S. Ct. at 2053 (quoting 17 C.F.R. §§ 201.111(c)) (SEC ALJs); *see* 16 C.F.R. § 3.42(c) (empowering FTC ALJs to, among other things, "receive evidence", "conduct . . . hearings", "administer oaths", "rule upon . . . motions", and "regulate the course of the hearings and the conduct of the parties and their counsel"). Both are empowered to "make and file initial decisions", which may then be appealed to the respective full Commission. 16 C.F.R. §§ 3.42(c)(9), 3.52(a)(1) (FTC ALJs); *see* 17 C.F.R. § 201.360(a)(1) (SEC ALJs). And both "have all powers necessary" to "dispos[e] of" the proceedings over which they preside. 16 C.F.R. § 3.42(c) (FTC ALJs); *see* 17 C.F.R. §§ 201.111, 200.14(a) (SEC ALJs).

The Commission has relied on a footnote in *Free Enterprise Fund* to argue that its ALJs can be afforded dual-layer protection without violating Article II because FTC ALJs "perform adjudicative rather than enforcement or policymaking functions" and "possess purely recommendatory powers." *Free Enter. Fund*, 501 U.S. at 507 n.10; *see, e.g.*, *In re Axon Enter., Inc.*, No. 9389, Order Denying Resp't's Mot. to Disqualify the Administrative Law Judge 3-6 (Sept. 3, 2020). However, *Free Enterprise Fund* did not reach the question of whether ALJs are covered by its holding. The *Lucia* Court later made clear that they are. *See* 138 S. Ct. at 2049. And whether FTC ALJs perform adjudicative rather than enforcement or policymaking functions and possess recommendatory powers is not determinative after *Lucia*. *See id.* at 2060 (Breyer, J., concurring in part) (noting that if ALJs are "Officers", they may present a constitutional removal problem, since Congress has also provided ALJs with dual-layer removal protection—"just what *Free Enterprise Fund* interpreted the Constitution to forbid in the case of the Board members").

In any case, FTC ALJs have both adjudicative and policymaking functions (like members of the PCAOB addressed in *Free Enterprise Fund*). *See* 501 U.S. at 507 n.10; *id.* at

3148 (citing 15 U.S.C. §§ 7213-7215 (2006)); *see also* Kevin M. Stack, *Agency Independence After PCAOB*, 32 Cardozo L. Rev. 2391, 2409-10 (2011). In addition to their adjudicative functions, FTC ALJs engage in some policymaking by conducting rulemaking proceedings and ensuring that the rulemaking proceeds in an orderly fashion. *See* 16 C.F.R. §1.13. The Supreme Court has recognized that all "judges do engage in policymaking at some level", by exercising discretion concerning issues of public importance. *Chisom v. Roemer*, 501 U.S. 380, 399 n.27 (1991) (citation omitted). Any claim that FTC ALJs possess "purely recommendatory powers" is incorrect. *Free Enter. Fund*, 501 U.S. at 507 n.10. While the Commission may review an ALJ's decision, the Commission may also decide not to review an ALJ decision at all, in which case the ALJ's decision becomes final. 16 C.F.R. § 3.52(a)(1).[27] And in the past 26 years, the FTC has *never* reversed a decision in which an FTC ALJ found liability. Joshua D. Wright, Remarks at the Symposium on Section 5 of the Federal Trade Commission Act, *Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority* 6 (Feb. 26, 2015).

As the Supreme Court explained in *Seila L. LLC v. Consumer Financial Protection Bureau*, "[t]he Framers' constitutional strategy [wa]s straightforward: divide power everywhere except for the Presidency, and render the President directly accountable to the people through regular elections." 140 S. Ct. 2183, 2187 (2020). In that scheme, individual executive

[27] The Commission in *In re Axon* suggested that the Commission's ability to modify or set aside an ALJ decision means that the Commission, rather than the ALJ, is responsible for final agency decisions. *In re Axon Enter., Inc.*, No. 9389, Order Denying Resp't's Mot. to Disqualify the Administrative Judge 5 (Sept. 3, 2020). However, *Free Enterprise Fund* presumes that PCAOB members do not possess "purely recommendatory powers". Since PCAOB members' issuance of rules and impositions of sanctions are subject to the SEC's approval and alteration, FTC ALJs also cannot possess "purely recommendatory powers" simply because the Commission may review an ALJ's decision. 15 U.S.C. §§ 7217(b)-(c); *Free Enter. Fund*, 501 U.S. at 486.

officials will still wield significant authority, but that authority will remain subject to the ongoing supervision and control of the elected President. Through the President's oversight, "the chain of dependence [is] preserved", so that "the lowest officers, the middle grade, and the highest" all "depend, as they ought, on the President, and the President on the community". 1 Annals of Cong. 499 (1789) (J. Madison). The FTC's dual-protection structure for ALJs contravenes this carefully balanced system by vesting significant governmental power in the hands of a single individual who is neither elected by the people nor meaningfully controlled (through the threat of removal) by someone who is.[28]

B. The FTC's Internal Administrative Process Violates the Due Process Clause.

In addition to violating Article II, Complaint Counsel's challenge to the Transaction runs afoul of the Due Process Clause of the Fifth Amendment of the U.S. Constitution. "A fair trial in a fair tribunal is a basic requirement of due process". *Kaley v. United States*, 571 U.S. 320, 345 (2014) (quoting *In re Murchison*, 349 U.S. 133, 136 (1955)). This requirement applies to any adjudicative body, whether it be an administrative tribunal or a court. *Gibson v. Berryhill*, 411 U.S. 564, 579 n.17 (1973). Not only is a biased decision maker constitutionally unacceptable but our system of law has also "always endeavored to prevent even the probability of unfairness." *Republican Party of Minn. v. White*, 536 U.S. 765, 815 (2002) (quoting *In re Murchison*, 349 U.S. at 136). In *Withrow v. Larkin*, the Supreme Court held that the combination of investigative and adjudicative functions does not necessarily

[28] In addition, the single-layer constraint on the President's removal of the FTC Commissioners violates Article II. 15 U.S.C. § 41. The Solicitor General recently agreed in *Seila L. LLC*, that "[t]he reasoning for *Humphrey's Executor* [*v. United States*, 295 U.S. 602 (1935)]," which held that a single layer of good-cause protection is permissible under limited circumstances, "does not withstand careful analysis." *See* Br. for Resp't Supporting Vacatur, No. 19-7, 2019 WL 6727094, at *31, 45 (U.S. Dec. 9, 2019).

constitute a due process violation. 421 U.S. 35, 58 (1975). However, the Court also made clear that there are circumstances in which the combination of investigative and adjudicative functions can constitute a due process violation, as there are situations "in which experience teaches that the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable". *Id.* at 47. In *Williams v. Pennsylvania*, the Supreme Court held that "an unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case". 579 U.S. 1, 1905 (2016).[29]

As in *Williams*, the FTC's challenge to the Transaction here creates an unconstitutional potential bias because the same people who voted out the complaint against Respondents—and have prosecuted the case against them—will adjudicate it.

- All four of the then-sitting Commissioners—three of whom will decide the appeal of this case—voted out the complaint. (PFF ¶ 1191.) Chairperson Khan was not on the Commission at the time the Complaint was issued, but she subsequently joined the Commission on June 15, 2021 and authorized this matter to proceed in lieu of litigation in federal court. (PFF ¶ 1192.) Moreover, Ms. Khan's articles were presented to Respondents' experts during depositions. (PFF ¶ 1193.) Thus, absent an unprecedented change in the composition of the Commission, the Commission will pass judgment on itself. *See* Malcolm B. Coate & Andrew N. Kleit, *The Political Economy of Federal Trade Commission Administrative Decision Making in Merger Enforcement* 3 n.4 (Working Paper No. 210, 1995) ("Whenever the same people who issued a complaint later decide whether it should be dismissed, concern about at least the appearance of fairness is inevitable".)

- All four of the then-sitting Commissioners—three of whom will decide the appeal of this case—also participated in the prosecution of this case by interviewing witnesses and rejecting settlement offers by Respondents before filing the complaint. (PFF ¶ 1195.) Each of these then-sitting Commissioners individually sought out witnesses and made judgments about their credibility before voting out the complaint in both the FTC and federal court. (PFF ¶ 1195.1 (emails from Commissioners Slaughter, Wilson, Phillips, and Chopra seeking and scheduling interviews with Exact's CEO Kevin Conroy). Interviewing witnesses is precisely what prosecutors are authorized

[29] Some lower court cases before *Williams* can be read to authorize an agency to combine investigatory and adjudicatory functions, but they are clearly limited in the wake of *Williams*. *See, e.g.*, *Kennecott Copper Corp. v. FTC*, 467 F.2d 67 (10th Cir. 1972); *FTC v. Cinderella Career & Finishing Schs.*, 404 F.2d 1308 (D.C. Cir. 1968).

to do and what judges are prohibited from doing. ABA Standards for Criminal Justice § 3-3.4(c) ("The prosecutor . . . should seek to interview all witnesses"); Model Rules of Jud'l Conduct R. 2.9 (2020) ("A judge shall not investigate facts in a matter independently"). Before filing complaints in the FTC and federal court, all four of the Commissioners at the time also acted as prosecutors by rejecting Illumina's efforts to resolve the case and instead insisting on proceeding to trial. (PFF ¶ 1195.3); *see* Mot. for Conference to Facilitate Settlement 3-4, *In re Illumina, Inc. & GRAIL, Inc.*, No. 9401 (Jul. 13, 2021); Fed. R. Crim. P. 11(c)(1) ("An attorney for the government . . . may discuss and reach a plea agreement. The court must not participate in these discussions.")

- All four of the then-sitting Commissioners—three of whom would decide the appeal of this case—agreed to withdraw the federal case that would have allowed a federal district judge to decide whether the Transaction should stand, reserving that right to themselves. (PFF ¶ 1196.) Just as prosecutors are free to withdraw their charges at any time, Commissioners can withdraw their complaint at any time by vote rather than by a motion to withdraw or dismiss. *See* 15 U.S.C. § 45(b); Press Release, Federal Trade Commission, Federal Trade Commission Withdraws Remaining Case against AbbVie after Supreme Court Decision Strips Consumers of Relief (July 30, 2021) (announcing the Commission's withdrawal of its complaint based solely on the Commissioners' vote).

An accuser lacks the necessary neutrality to determine the merits of its own allegations. (PFF ¶ 1197.) For example, a study of SEC adjudications showed that when the SEC judged cases in which it brought charges in fiscal years 2007 through 2015, the SEC won against over 93% of defendants. (*See* PFF ¶ 1197.1 (Urska Velikonja, *Are the SEC's Administrative Law Judges Biased? An Empirical Investigation*, 92 Wash. L. Rev. 315, 369 (2017).) A research project concerning potential bias at the FTC in merger challenges decided between 1956 and 1992 found that the "ability of commissioners to act as both prosecutor and judge in a particular matter can significantly increase the likelihood of a merger order". (PFF ¶ 1197.1 (Malcolm B. Coate & Andrew N. Kleit, *Does it Matter that the Prosecutor is also the Judge? The Administrative Complaint Process at the Federal Trade Commission*, 19 Managerial & Decision Econ. 1, 9 (1998).) And a study of the legal profession found that lawyers—such as FTC Commissioners acting as prosecutors—tend to view the merits of their clients' cases too favorably. Zev J. Eigen & Yair Listokin, *Do Lawyers Really Believe Their Own Hype and*

Should They? A Natural Experiment, 41 J. Legal Stud. 239, 263-64 (2012) (showing that the Commission cannot be neutral adjudicators if they themselves authorized enforcement).

As a former FTC Commissioner has acknowledged, once the Commission votes out a complaint, it finds in favor of itself 100% of the time. Joshua D. Wright, Comm'r, FTC, Remarks at the Symposium on Section 5 of the Federal Trade Commission Act, *Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority* 6 (Feb. 26, 2015).[30] According to former Commissioner Wright:

> The FTC has voted out a number of complaints in administrative adjudication that have been tried by administrative law judges in the past nearly twenty years. In each of those cases, after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability. **In other words, in 100 percent of cases where the administrative law judge ruled in favor of the FTC staff, the Commission affirmed liability; and in 100 percent of the cases in which the administrative law judge [ ] found no liability, the Commission reversed. This is a strong sign of an unhealthy and biased institutional process**. By way of contrast, when the antitrust decisions of federal district court judges are appealed to the federal courts of appeal, plaintiffs do not come anywhere close to a 100 percent success rate—indeed, the win rate is much closer to 50 percent.

Id. (footnote omitted, emphasis added). To this day, the Commission has never decided against itself in any merger challenge.

The unusual posture of this case further highlights the way that investigative and adjudicative powers have been mingled in this case. (PFF ¶ 1198) Unlike most cases where the FTC has notice of a transaction, the Transaction here has already been consummated, and

[30] Similarly, a former SEC Commissioner has admitted that despite needing to act with the "cold neutrality of an impartial judge" when acting in a judicial capacity, after prosecuting violations, the SEC had "a vested interest in ensuring that a particular result [was] reached [and] that particular policies [were] protected or advanced" such that "fairness and the appearance of fairness . . . [were] left behind". Edward H. Fleischman, *Toward Neutral Principles: The SEC's Discharge of Its Tri-Functional Administrative Responsibilities*, 42 Cath. U. L. Rev. 251, 260-61 (1993) (citations omitted).

Complaint Counsel seeks to unwind it. (PFF ¶ 1198.1.) This is no accident. (PFF ¶ 1198.2.) Complaint Counsel initially filed a complaint in federal court seeking to enjoin the Transaction—but then unilaterally moved to dismiss its own complaint, in favor of a forum in which the Commissioners will judge their own allegations. (PFF ¶ 1198.2.) In its papers supporting the motion to dismiss, Complaint Counsel openly admitted that it knew Respondents did not agree that they were "prohibited from closing", and chose to dismiss its own case anyway. (PFF ¶ 1198.3.) Complaint Counsel specifically reserved the right to re-file its federal action "if the [Respondents] attempt to close", but Respondents actually did close—and Complaint Counsel still chose not to re-file. (PFF ¶ 1198.4.) Then, in the middle of trial in this action, which was the first-ever challenge under the 2020 Vertical Merger Guidelines, the Commission suddenly withdrew those Guidelines, trying to slant the playing field in Complaint Counsel's favor. (PFF ¶ 1198.5.) Complaint Counsel plainly did not believe that it would succeed in federal court, and instead opted to try this case "on its own turf", where the Commission itself will be the ultimate administrative arbiter. (PFF ¶ 1198.6.) The FTC's approach here is precisely the type of mingling of investigative and adjudicative powers that violates due process rights.

C. The FTC's Structure and Procedural Rules Violate the Equal Protection Clause.

The constitutional infirmity of Complaint Counsel's case is not limited to the fact that it violates Article II and the Due Process Clause. Complaint Counsel's challenge to the Transaction should also be rejected, because it violates the Equal Protection Clause of the U.S. Constitution.

The Equal Protection Clause of the Fifth Amendment commands that the government shall not "deny to any person within its jurisdiction the equal protection of the laws". U.S. Const. amend. XIV, § 1; *U.S. v. Windsor,* 570 U.S. 744, 774 (2013) ("The liberty

protected by the Fifth Amendment's Due Process Clause contains within it the prohibition against denying to any person the equal protection of the laws.") (citing *Bolling v. Sharpe*, 347 U.S. 497, 499–50 (1954)). "The guaranty of 'equal protection of the laws is a pledge of the protection of equal laws'". *Romer v. Evans*, 517 U.S. 620, 633-34 (1996) (quoting *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942)). Thus, the Equal Protection Clause protects against "arbitrary and irrational discrimination" by the Government, *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 83 (1988), and demands that "all persons similarly situated should be treated alike", *Tennessee v. Lane*, 541 U.S. 509, 522 (2004) (quoting *Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 439 (1985)). Any difference in treatment "run[s] afoul of the Equal Protection Clause" when there is no "rational relationship between the disparity of treatment and some legitimate governmental purpose". *Montgomery v. Louisiana*, 577 U.S. 190, 231 (2016).

No one can seriously dispute that the parties to a merger challenged by the FTC are treated very differently from the parties to a merger challenged by DOJ. For example:

- Difference in the forum for adjudicating the merits. The parties to a merger challenged by DOJ are entitled to have the challenge adjudicated in a U.S. district court. 15 U.S.C. § 25. In contrast, the parties to a merger challenged by the FTC are not entitled to have the matter adjudicated in federal district court; they can be compelled to litigate in an internal administrative proceeding, U.S. district court, or both—at the FTC's election. 15 U.S.C. § 45(b). As this case demonstrates, parties can even be forced into the FTC's internal administrative proceeding after a federal district court case is well underway.

- Difference in the preliminary injunction standard. The parties to a merger challenged by DOJ cannot be preliminarily enjoined except upon the traditional four-part showing under the common law: (i) the probability of success on the merits; (ii) the significance of the threat of irreparable harm to plaintiff if the injunction is granted; (iii) the balance between this harm and the injury the injunction would inflict on the defendant; and (iv) the public interest. Dep't of Justice, Antitrust Div., Antitrust Division Manual IV-14 (4th ed. 2008); *United States v. Gillette Co.*, 828 F. Supp. 78, 80 (D.D.C. 1993). The parties to a merger challenged by the FTC, however, can be enjoined upon a lesser showing under Section 13(b) of the FTC Act, which courts

have interpreted as "a unique 'public interest' test . . . rather than the more stringent, traditional 'equity standard for injunctive relief." *FTC v. Exxon Corp.*, 636 F.2d 1336, 1343 (D.C. Cir. 1980); *see also See FTC v. Heinz*, 246 F.3d 708, 714 n.5 (D.C. Cir. 2001);15 U.S.C. § 53(b)(2) ("Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest . . . a preliminary injunction may be granted").

- Difference in substantive legal standards and policies. The parties to a merger challenged by DOJ are guided by the Vertical Merger Guidelines. *See* Press Release, Federal Trade Competition, FTC and DOJ Issue Antitrust Guidelines for Evaluating Vertical Mergers (June 30, 2020). However, the parties to a merger challenged by the FTC may not be, as a majority of the current FTC Commissioners repudiated the Vertical Merger Guidelines during the pendency of this proceeding. *See* Press Release, Federal Trade Commission, Federal Trade Commission Withdraws Vertical Merger Guidelines and Commentary (Sept. 15, 2021).

- Difference if a U.S. district court rules against the challenge. The parties to a merger challenged by DOJ are subject to a single proceeding in which DOJ has no legal recourse in the event it loses, except to appeal to the circuit court. 28 U.S.C. § 1291; Fed. R. App. P. 3(a)(1). In contrast, the parties to a merger challenged by the FTC run the risk of the FTC proceeding in two forums simultaneously (federal court and an administrative proceeding) or challenging the merger in U.S. district court and if the court rules against the challenge, retrying the entire merits proceeding in an administrative proceeding within the FTC itself. 15 U.S.C. § 45(b). The FTC possesses "a significant advantage that DOJ lacks in negotiating a settlement, as few parties will want to litigate a full administrative trial and face the risk of expensive and disruptive divestitures". Antitrust Modernization Comm'n, Report and Recommendations 129, 142 (2007). In addition, if the FTC loses before an FTC ALJ, the Commission may itself reverse that decision as to both factual and legal findings. 16 C.F.R. § 3.54(b).

- Difference in the independence of the factfinder. The parties to a merger challenged by DOJ are entitled to an independent factfinder—an Article III judge appointed by the President and confirmed by the Senate, with no allegiance to DOJ. 15 U.S.C. § 25. In contrast, parties to a merger challenged by the FTC in an internal administrative proceeding face an ALJ whom the FTC can replace at any time and can reverse on a *de novo* review, and appeal to the very Commissioners who voted out the complaint and directed its prosecution. 16 C.F.R. §§ 3.42(a), 3.54.

- Difference in applicable procedural and evidentiary rules. The parties to a merger challenged by DOJ are entitled to the protections of the Federal Rules of Civil Procedure and the Federal Rules of Evidence. *See* 15 U.S.C. § 25. Failure by DOJ to abide by the applicable procedural rules results in exclusion of evidence and potential sanctions against DOJ. Antitrust Div., U.S. Dep't of Just., Template Pursuant to Section 3(a) of the ICN Framework on Competition Agency Procedures 3. In contrast, the parties to a merger challenged by the FTC are subject to rules created by the FTC itself, do not necessarily enjoy the protections of the Federal Rules of Civil

Procedure or the Federal Rules of Evidence, and must petition their accuser for relief from subpoenas and Civil Investigative Demands. 16 C.F.R. § 3.1. The FTC has even changed procedural rules when ALJs have ruled against it. (*See* Final Pretrial Hearing Tr. 66:8–13 (Aug. 23, 2021) ("In fact, a lot of the rules that we abide by were – let's just say the rules were changed after I came to the Federal Trade Commission because of rulings I continually made applying Federal Rule of Evidence. That's all I'll say about that. But just remember, there's no jury. It's a bench trial.").)

- Difference in the permanent injunction forum. The parties to a merger challenged by DOJ are entitled to litigate the issue in federal court alone, often in a consolidated proceeding at which the issue of preliminary and permanent injunctive relief are decided at the same time. (PFF ¶ 1207); 15 U.S.C.§ 25. By contrast, the parties to a merger challenged by the FTC must litigate preliminary injunctions in federal district court and permanent injunctions in an administrative proceeding subject to review by the FTC. 15 U.S.C. § 53(b).

- Difference in ability to change a merits decision before circuit court appeal. The parties to a merger challenged by DOJ face no risk that DOJ will change the district court's merits decision before appeal to the circuit court, as DOJ has no power to do so. By contrast, the parties to a merger challenge in the FTC's administrative proceedings run the significant risk that the Commission will change a merits decision, including a decision that is adverse to the FTC, prior to appeal to the circuit court. 15 U.S.C. § 45(c); 16 C.F.R. § 3.54(b). The Commission is empowered to ignore an ALJ's determinations in their entirety and substitute the Commission's own legal and factual findings prior to appeal. 16 C.F.R. § 3.54. In fact, in the past 20 years, the FTC has reversed all but one decision in which the ALJ. Joshua D. Wright, Comm'r, FTC, Remarks at the Symposium on Section 5 of the Federal Trade Commission Act, *Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority* 6 (Feb. 26, 2015); *see, e.g.*, *In re Schering-Plough Corp.*, No. 9297, 2003 WL 25797209 (FTC Dec. 8, 2003); *In re Union Oil Co. of Cal.*, No. 9305, 2004 WL 5662245 (FTC July 6, 2004); *In re Rambus Inc.*, No. 9302 (FTC July 31, 2006); *In re Realcomp II, Ltd.*, No. 9320, 2007 WL 6936319 (FTC Oct. 30, 2009); *In re LabMD, Inc.*, No. 9357 (FTC July 28, 2016); *In re Impax Lab'ys, Inc.*, No. 9373, 2019 WL 1552939 (FTC Mar. 28, 2019).

- Difference in circuit court appellate standards. The parties to a merger challenged by DOJ are entitled to factual review under the clearly erroneous standard. *Baker Hughes, Inc.*, 908 F.2d at 983 (citing Fed. R. Civ. P. 52(a)). In contrast, parties to a merger challenged by the FTC are subject to factual review under the lesser, substantial-evidence standard. *See Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1385 ("Our only function is to determine whether the [FTC's] analysis of the probable effects of these acquisitions . . . is so implausible, so feebly supported by the record, that it flunks even the deferential test of substantial evidence.").

There is no rational basis for these differences, which can be outcome determinative. Treating parties differently based on whether their merger is reviewed by the

FTC instead of DOJ is unrelated to any legitimate governmental purpose. The choice of whether a challenge is brought by DOJ or the FTC is sorted out by the agencies themselves through an informal, non-public, unwritten process called "clearance". (PFF ¶ 1210.) At times, the FTC and DOJ have decided which agency will handle a case by a coin flip. (PFF ¶ 1211.)

Even when the choice of reviewing agency is not the product of a coin toss, the clearance process is "opaque at best", often resulting in disputes between the two agencies over which agency will investigate a certain matter rather than an allocation based on reason. (PFF ¶ 1212.) A former director of the FTC's Bureau of Competition from 2013 to 2017 has stated that "every deal [she had] worked on [had] been mired in a clearance dispute between the agencies . . . even for industries . . . she would have thought would clearly fall into one agency's particular expertise". (PFF ¶ 1213.)

While a 2002 Clearance Agreement reformed the clearance process and sought to capitalize on each agency's "industry-specific knowledge", allocating merging parties based on past industry-specific knowledge is no less arbitrary. (PFF ¶ 1214.) Which agency has responsibility for (and purports to have expertise in) a particular industry is an accident of history. (PFF ¶ 1215.) Industry-specific knowledge might explain why a particular agency should handle a certain matter, but it does not explain why particular merging parties in an industry ought to receive more or less procedural protections. Although there might be a reason for the given agency to review a merger in a specific industry (e.g., recent experience), there is no rational basis for favoring one industry over another.

* * *

To wrap up, there are constitutional defects in Complaint Counsel's case, on top of its inability to prove a relevant downstream or upstream market, its failure to substantiate its foreclosure allegations, its disregard of the Open Offer, its selective reading of the evidentiary

record, and its failure to account for the numerous efficiencies the Transaction will generate. To be specific, the FTC's case violates Article II because FTC ALJs are afforded dual-layer protection from presidential review, it violates the Due Process Clause because the FTC is acting simultaneously as prosecutor, judge, and jury, and it violates the Equal Protection Clause because it irrationally deprives Respondents of structural and procedural protections they would possess in a challenge brought by DOJ.

VI. COMPLAINT COUNSEL'S CASE RUNS COUNTER TO THE OVERWHELMING PROOF AND RESTS ON "EVIDENCE" THAT IS INADMISSIBLE AND/OR DESERVING OF NO WEIGHT.

Spellbound by its own allegations, Complaint Counsel casts a blind eye at the unrebutted testimony of witnesses from Illumina, GRAIL and disinterested third parties. It also ignores the largely unchallenged testimony of eight experts, called by Respondents, including three former chief economists of DOJ and the only two practicing physicians to be called as witnesses. Instead, Complaint Counsel rests on: (1) the opinions of three economists who are either unqualified to offer the opinions they provide or failed to support their opinions with reliable evidence; (2) selective citations from alleged third-party test developers who have a self-interest in derailing the Transaction; and (3) IH transcripts and other documents that are inadmissible and/or deserving of little weight.

A. The Illumina and GRAIL Witnesses and Disinterested Third Parties.

As stated above (*see* Statement of Facts *supra*) and demonstrated in Respondents' Proposed Findings of Fact, the unrebutted testimony of the Illumina and GRAIL witnesses uniformly undermines Complaint Counsel's case. For example:

Francis deSouza, Illumina's CEO, testified to the numerous efficiencies that will result from the Transaction. He explained how the Transaction will accelerate the availability of Galleri around the world, benefitting the public writ large. (deSouza, Tr. 2234-25.) In addition,

he explained why Illumina does not have any incentive to raise prices to, or not cooperate with, any GRAIL rival or potential GRAIL rival because that would jeopardize Illumina's core business of selling sequencers and consumables (PFF ¶ 1243); and raising sequencing costs would not be effective due to the small percentage of sequencing costs in the overall cost of an MCED test (PFF ¶ 1246.) He further explained why the Open Offer resolves any legitimate objections to the transaction, (PFF ¶ 1252) as it guarantees oncology customers the same access to products and services as GRAIL or any other Illumina customer. (PFF ¶ 1253.) Complaint Counsel did not undermine any of this testimony on cross examination. Despite Complaint Counsel's attempts to impeach Mr. deSouza with his IH testimony in an attempt to undermine his trial testimony on efficiencies, Mr. deSouza emphasized the IH testimony used by Complaint Counsel was taken out of context and does not in any way change his conviction that the Transaction will result in significant efficiencies. (PFF ¶ 1220.) Complaint Counsel also attempted to undermine the benefits of the Open Offer but Mr. deSouza reaffirmed that Illumina is committed to abiding by the terms of the Open Offer and to treating all its oncology customers equally, and that he was willing to change the Open Offer in any way if the FTC thought it was insufficient. (PFF ¶¶ 1252.1, 1259.)

Dr. Alex Aravanis, Illumina's Chief Technology Officer, testified that the reunification of Illumina and GRAIL will result in substantial efficiencies that could not be otherwise achieved absent the Transaction, including lives saved due to acceleration, R&D efficiencies, international expansion, and operational and lab efficiencies. (PFF ¶¶ 1325–47.) As a founder of GRAIL, and its former Chief Technology Officer, he is uniquely positioned to testify on this subject. Dr. Aravanis also offered testimony undermining Complaint Counsel's foreclosure theory, including that Illumina faces competition from several NGS companies

including Thermo Fisher, BGI, Omniome (now part of PacBio), Oxford Nanopore, and Genapsys. (PFF ¶¶ 1304–14.) Complaint Counsel did not undermine any of this testimony on cross examination. Most importantly, Complaint Counsel did not challenge any of Dr. Aravanis' testimony on efficiencies. (PFF ¶ 1325.1.)

Jay Flatley, Illumina's former Chairman and CEO, testified that Illumina's board was unanimous in its approval of the GRAIL acquisition (PFF ¶ 1355), and that the board concluded that the merger would accelerate Galleri's FDA approval because Illumina has significant experience in regulatory issues, which GRAIL lacks. (PFF ¶¶ 1359–60.) Mr. Flatley also testified that the board concluded that: (1) the Transaction would accelerate Galleri's payor reimbursement because Illumina has an experienced market access group it can leverage to aid GRAIL get reimbursement; (2) the Transaction would streamline the supply chain because the combined entity would be able to combine volumes and therefore reduce costs; (3) the Transaction would streamline operations because the combined entity would be able to integrate and leverage the data across multiple tests for a given patient; (4) the Transaction would accelerate Galleri's international commercial expansion because Illumina has a global infrastructure GRAIL can leverage to expand its reach internationally; (5) the Transaction will result in R&D efficiencies because a combined company could take advantage of the data that comes from the international expansion, integrate that data, and use deep learning algorithms to improve the accuracy of the Galleri test; and (6) the Transaction would accelerate Galleri's market adoption and as a result, save lives. (PFF ¶¶ 1356–68.) Complaint Counsel did not undermine any of this testimony on cross examination.

Dr. Phil Febbo, Illumina's Chief Medical Officer, explained Illumina's ability to accelerate Galleri's FDA approval because it has an experienced regulatory team that has

accumulated significant FDA expertise over the years. (PFF ¶¶ 1372, 1383–85.) Dr. Febbo testified that Illumina has deep experience working with the FDA, educating the agency regarding NGS technology and obtaining approval for two NGS sequencers and a clinical test. (PFF ¶¶ 1372, 1383–85.) Dr. Febbo pointed out that GRAIL cannot achieve the same acceleration because it does not have FDA experience comparable to Illumina's. (PFF ¶ 1386.) Dr. Febbo further testified that Galleri's FDA acceleration also could not be achieved by GRAIL hiring consultants, by hiring Illumina's regulatory personnel or via contract because: (1) consultants do not usually have the same experience as in-house teams and are not as effective (Febbo, Tr. 4365); (2) GRAIL would not share its "secret sauce" proprietary information with Illumina in an arm's length relationship; (3) Illumina does not provide regulatory consulting services to its customers and (4) the knowledge of Illumina's regulatory department is dispersed within the regulatory team and dispersed among the institution, one or two employees serving as consultants to GRAIL would not have the same effectiveness as a team that is cross-functionally integrated within Illumina. (PFF ¶¶ 1398–1401.) Complaint Counsel did not undermine any of this testimony on cross examination.

Joydeep Goswami, Illumina's chief strategy and corporate development officer, testified to Illumina's strategy with respect to IVD partnerships. (PFF ¶ 1407.) Complaint Counsel argues that distributed (or "kitted") IVD tests are critical to achieving widespread adoption of an MCED test and that Illumina has both the ability and incentive to deny MCED test developers IVD rights. Dr. Goswami debunked these theories by testifying that all test developers start with a LDT, that only some MCED test developers may seek single site PMA (ssPMA) FDA approval and fewer still may seek FDA approval for a kitted IVD test. (PFF ¶¶ 1412–14.) Dr. Goswami pointed out that companies like Myriad and Exact have shown that

you can scale a test effectively without a distributed IVD model (PFF ¶ 1417) and GRAIL, the only company with a MCED test on the market, has not expressed any intent to pursue a distributed IVD kit (PFF ¶ 1417). Dr. Goswami also testified that Illumina has no involvement in the commercialization of non-kitted tests like LDTs and no involvement in test developers obtaining ssPMA approval from the FDA. (PFF ¶ 1413.) [redacted] Dr. Goswami reaffirmed that Illumina has no ability to disadvantage its competitors through the IVD partnerships because it does not receive proprietary information relating to the operation of the IVD partner's test and maintains effective confidentiality policies and measures that ensure that any confidential information is not disclosed beyond a limited set of employees. (PFF ¶¶ 1418–19.) Finally, Dr. Goswami testified that Illumina's Open Offer commits Illumina to assisting customers, including MCED test developers, who want to develop IVD kits and allows customers to enter an IVD agreement with Illumina at any time from the close of the Transaction until six years after the close of the Transaction. (PFF ¶ 1427.) Complaint Counsel did not undermine any of this testimony on cross examination.

Ammar Qadan, Illumina's Vice President and Global Head of Market Access, explained Illumina's ability to accelerate Galleri's payor reimbursement, based on Illumina's past work expanding global market access for NIPT, tumor comprehensive genetic profiling and whole genome sequencing. (PFF ¶¶ 1444–59.) Mr. Qadan explained that Illumina often uses evidence gathered through its risk-sharing agreements with insurers to drive expansion of coverage and will do the same for Galleri. (PFF ¶¶ 1460–61, 1472–77.) Mr. Qadan further

testified that Illumina is capable of contributing to the development of evidence of clinical and economic utility in a way that will accelerate the availability of Galleri on a large scale and Illumina is capable of generating that type of evidence in a way that will help to accelerate the availability of Galleri on a broad scale. (PFF ¶¶ 1472–77.) For example, Mr. Qadan testified that Illumina's existing partnership with UnitedHealth Group will allow Illumina to accelerate Galleri's market adoption because Illumina has plans to add Galleri to the scope of the partnership. (PFF ¶ 1489.) Mr. Qadan also testified that a team of consultants could not provide the functionality for GRAIL that the Illumina market access could because they would lack the institutional expertise and Illumina would not provide its market access services on a contractual basis. (PFF ¶ 1483.) Complaint Counsel did not undermine any of this testimony on cross examination.

Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Region, testified to Illumina's relationship with its customers and the commitments Illumina has made through the Open Offer. (PFF ¶ 1505.) Among other things, Ms. Berry explained that the Open Offer (binding on Illumina now that the Transaction has closed) commits Illumina to provide uninterrupted supply of sequencing instruments and consumables; not increase the price of any of the supplied sequencing instruments or consumables; decrease the cost of sequencing on Illumina's highest throughput sequencing instrument, using the highest throughput consumable, by at least 43%; provide access to sequencing products at the same pricing as GRAIL; submit to an annual audit by an independent third-party auditor confirming compliance with the terms of the supply commitments; and allow for disputes on supply terms to be adjudicated through baseball-style arbitration. (PFF ¶¶ 1511–24.) Complaint Counsel did not undermine any of this testimony on cross examination.

John Leite, Illumina's former Vice President of Clinical Business Development, testified concerning Illumina's practices regarding its IVD partnerships. Contrary to Complaint Counsel's assertions that Illumina has a history of using its IVD partnership program to disadvantage its competitors, using the Roche partnership as an example, Mr. Leite testified that while Illumina considered that Roche's tests would compete with its TSO-500 test, it decided that the benefits from partnering with Roche outweighed any potential losses to Illumina due to competition. (PFF ¶¶ 1542–43.) [redacted] Complaint Counsel did not undermine any of this testimony on cross examination.

Hans Bishop, then-Chief Executive Officer of GRAIL, testified that being part of Illumina will increase GRAIL's chances of being successful with its PMA, offering experience that will aid scaleup and innovation and providing stability to mitigate financial risk. (PFF ¶ 1586.) He explained that GRAIL is at a delicate and risky inflection point as it transitions from an R&D company to a commercial company. (PFF ¶ 1577.) Bishop further testified that the acquisition will bring scale, cost, engineering and manufacturing benefits which will directly

impact test price. (PFF ¶ 1591.) Contrary to Complaint Counsel's theory that Galleri will be competing directly with all the other MCED tests in development, Mr. Bishop testified that GRAIL does not consider other early detection liquid biopsy developers as competition. (PFF ¶¶ 1568–75.) Complaint Counsel did not undermine any of this testimony on cross examination.

Josh Ofman, [redacted]

[redacted]

Aaron Freidin, GRAIL's Senior Vice President of Finance, testified the benefits resulting from the Transaction could not be achieved by alternative means, such as an initial public offering (IPO). (PFF ¶ 1650.) According to Mr. Freidin, that is not a viable alternative for GRAIL as they would not meet their break-even target of $2 billion and would need to return to the markets, thus exposing them to even greater risks and causing more delays than being acquired. (PFF ¶ 1650.) Mr. Freidin testified that the Transaction would allow GRAIL to feel secure about its future funding and it would de-risk capital needs and accelerate GRAIL's ability to put capital to work as Illumina is a multi-billion-dollar profitable business that generates cash flow. (PFF ¶ 1638.) Mr. Freidin explained that even if GRAIL were to successfully raise capital through the capital markets, it wouldn't come with all the expertise and infrastructure that Illumina has. (PFF ¶ 1650.) Mr. Freidin further testified to the various efficiencies that will result from the Transaction: Illumina would help accelerate commercialization as they sell multiple products in various sectors, have the ability to execute and provide reagents and tests to their customers and have the demonstrated capabilities and skills that GRAIL is building (PFF ¶ 1641); Illumina's previous work with Verinata in NIPT and its experience running labs and processing tests can facilitate GRAIL's efforts to improve its centralized scaled laboratory operations (PFF ¶ 1647); Illumina would accelerate international expansion as they have an international footprint with about 50 percent of their revenue coming from outside of the U.S., whereas GRAIL is currently focused on the U.S. domestic market with only about 10-20 employees in the U.K facilitating their only international study (PFF ¶ 1648–49.) Complaint Counsel did not undermine any of this testimony on cross examination.

Arash Jamshidi, [redacted]

Complaint Counsel did not undermine any of this testimony on cross examination.

Chris Della Porta, [redacted]

[redacted] Complaint Counsel did not undermine any of this testimony on cross examination.

The testimony of disinterested third parties is similarly supportive of Respondents' case.

Dr. William Cance, the Chief Medical and Scientific Officer of the American Cancer Society (ACS), testified the early detection of cancer will lead to a greater likelihood of curing cancer. (PFF ¶ 1920.) The ACS does not otherwise take a position on the Transaction. (PFF ¶ 1920.) The ACS has done no analysis that shows the acquisition would result in any loss of innovation in MCED tests or that it would raise the costs of developing MCED tests. (PFF ¶ 1920.)

Matthew Strom is a Managing Director with Morgan Stanley's healthcare investment banking group. (PFF ¶ 1845.) Morgan Stanley has been GRAIL's exclusive financial advisor for the last four years including for the Transaction. (PFF ¶ 1845.) [redacted]

[redacted]

Jorge Velarde, Singular's Senior Vice President of Corporate Development and Strategy testified that Singular intended to launch an NGS platform (the G4 sequencer) by the end of 2021, which happened on schedule, undermining Complaint Counsel's claim that there are no near-term alternatives to Illumina. (PFF ¶ 1902.) Singular anticipates that its NGS platform can replace Illumina's MiSeq, HiSeq, NextSeq and, in some cases, NovaSeq platforms. (PFF ¶ 1908.) Singular believes its NGS platform has competitive advantages compared to Illumina's NGS platforms, (PFF ¶ 1909) [redacted] and Singular's NGS platform was designed so that it doesn't disrupt customers' workflows when switching from Illumina. (PFF ¶ 1910.)

[redacted]

B. Leading Independent Experts.

Although they do not bear the burden of proof, Respondents called a number of expert witnesses to address Complaint Counsel's allegations. Among them were three former chief economists of DOJ (Dr. Carlton, Dr. Willig and Dr. Katz), a former assistant chief

economist at DOJ (Ms. Guerin-Calvert), two practicing physicians (Dr. Cote and Dr. Abrams), a medical academic professional (Dr. Deverka) and an accounting expert (Mr. Rock).

Dennis Carlton, Professor of Economics at the University of Chicago Booth School of Business, and Deputy Assistant Attorney General for Economics in the Antitrust Division of the U.S. DOJ, testified that: (1) vertical mergers generate efficiencies and are unlikely to cause significant competitive harm except in narrow circumstances not present here (PFF ¶¶ 1938–39); (2) Illumina does not have an incentive and ability to foreclose or raise the costs of rivals post-merger to significantly harm competition (PFF ¶ 1942); (3) Illumina does not have an incentive and ability to withhold key information and expertise post-merger to significantly harm competition in kitted IVD tests (PFF ¶ 1943); (4) the merger will likely create substantial efficiencies that will benefit customers and patients (PFF ¶¶ 1944–46); and (5) Dr. Scott Morton makes several theoretical and empirical errors that reveal her analysis lacks a reliable foundation (PFF ¶¶ 1940–41).

Dr. Robert Willig, Professor of Economics and Public Affairs Emeritus at the Woodrow Wilson School at Princeton University, and former Deputy Assistant Attorney General for Economics in the Antitrust Division of the U.S. DOJ opined that: (1) Dr. Scott Morton's market definition is speculative, and simultaneously overbroad and overly narrow (PFF ¶¶ 2009–13); (2) the substantial investments by MCED developers cut against Complaint Counsel's theory of anti-competitive harm (PFF ¶¶ 2014–18); and (3) Dr. Scott Morton's bargaining example is untethered to the facts of the marketplace and is not robust (PFF ¶¶ 2019–21).

Michael Katz, Professor Emeritus, Haas School of Business & Department of Economics at University of California, Berkeley, and former Deputy Assistant Attorney General for Economics in the Antitrust Division of the U.S. DOJ, testified that: (1) Professor Scott

Morton has failed to define the relevant product market reliably (PFF ¶¶ 2044–48); (2) Complaint Counsel's theories of anticompetitive effects are belied by the actions of firms in the marketplace (PFF ¶¶ 2049–53); and (3) Dr. Scott Morton's analysis of the impact of the proposed acquisition through the economic theory of bargaining is flawed and fails to establish that the proposed transaction would substantially lessen competition (PFF ¶¶ 2054–56).

Marguerite Guerin-Calvert, President and Senior Managing Director of FTI Consulting's Center for Healthcare Economics and Policy testified that: (1) the Open Offer covers the economically necessary set of terms to prevent the alleged competitive harm arising from the merger in both the short and long term (PFF ¶¶ 1993–95); (2) the Open Offer addresses the specific economic issues and concerns raised by the FTC, Dr. Scott Morton and certain Illumina customers (PFF ¶¶ 2000–05); (3) the Open Offer provides for effective monitoring and enforceability mechanisms (PFF ¶¶ 1996–99).

Dr. Richard Cote, Professor of Pathology and Immunology and Chair of the Department of Pathology and Immunology at the Washington University School of Medicine, testified that: (1) the only NGS-based multi-cancer screening test that has launched is GRAIL's Galleri test (PFF ¶ 1960); (2) the evidence to date shows that other cancer screening test developers are currently developing tests that will be complementary to GRAIL's Galleri test, rather than substitutable (PFF ¶¶ 1962–63); (3) the majority of test developers are, at minimum, more than five years behind GRAIL in their test development efforts (PFF ¶ 1961); (4) the evidence shows that a cancer screening test that cannot detect the cancer signal of origin using a liquid biopsy, is unlikely to be a substitute to a cancer screening test that can detect signal of origin, like Galleri, (PFF ¶ 1963); (5) there are alternative NGS platforms today that support multi-cancer screening tests and there are likely to be many more in the future, including by

2023 (PFF ¶¶ 1964–65, 1968–70); (6) given the long timeframes, all test developers pursuing cancer screening tests will have the opportunity to switch to non-Illumina NGS platforms without meaningfully affecting timeframes for development and FDA approval (PFF ¶¶ 1966–67); and (7) there are test developers today developing multi-cancer screening test using non-NGS platforms, including proteomics and microarray platforms (PFF ¶ 1971).

Dr. Richard Abrams, founder of Colorado Preventative Medicine, testified that: (1) primary care physicians play a key role in cancer screening today and will be primarily responsible for recommending MCED tests as they become commercially available and reimbursable in the future (PFF ¶ 2032); (2) primary care physicians will consider several factors (patient's risk factors for a particular cancer, the cancers that the test will be able to detect, the test specificity and sensitivity and other capabilities of the test, the cost of the test to the patient) when recommending or prescribing a multi-cancer screening test and will also need to decide whether any given multi-cancer screening test can be used as a substitute for or complement to other screening options (PFF ¶¶ 2033–34); (3) it would be inappropriate for a primary care physician today to order Galleri as a replacement for a high-sensitivity single-cancer test (e.g., recommended CRC screening such as a colonoscopy or Cologuard) (PFF ¶ 2035); and, (4) as Galleri is adopted more widely for clinical use, primary care physicians are likely to adopt Galleri as a complementary screening test in conjunction with other screening options (PFF ¶¶ 2036–38).

Dr. Patricia Deverka, Deputy Director of the Center for Translational and Policy Research on Personalized Medicine at the University of California at San Francisco, testified that: (1) GRAIL will face significant challenges in achieving private and public payor coverage for Galleri because of the complexity of the payor coverage processes, as well as the novelty and

specific features of the Galleri test (PFF ¶¶ 1979–87); (2) through the acquisition, Illumina will be able to help GRAIL overcome these challenges and accelerate coverage and reimbursement of Galleri, enabling it to achieve broad market coverage earlier than GRAIL would be able to on its own (PFF ¶¶ 1988–89); and (3) careful evaluation of Illumina's and GRAIL's market access capabilities reveals that GRAIL alone could not achieve the same reimbursement acceleration as could be achieved through acquisition by Illumina (PFF ¶ 1990.)

Robert Rock, Managing Director at AlixPartners, LLP, testified that an independent auditor can be effective in: (1) examining an entity's compliance with various terms of contracts; (2) performing agreed-upon procedures related to an entity's compliance with specified terms; (3) performing agreed-upon procedures related to an entity's internal controls. He also testified that: an independent auditor is fully capable of assisting Illumina in developing the appropriate procedures, controls and reporting; policies, procedures and reporting can be tailored to each assurance area specified in the Open Offer; the audit process can be effective in addressing allegations of a breach; the role of an auditor in the Open Offer is similar to that of a monitor and can perform the same essential oversight role; and, reporting and audit provisions are effective tools in promoting compliance. (PFF ¶ 2027.)

C. Complaint Counsel's Alleged Experts.

Unable to find support for its case in the individuals most knowledgeable about the industries at issue (the men and women at Illumina and GRAIL), Complaint Counsel sought to support its allegations with testimony of three alleged experts: Dr. Fiona Scott Morton, Dr. Amol Navathe and Dr. Dov Rothman. However, the testimony provided by these experts was either inadmissible (as described in Respondents' *in limine* motions and other objections) or so unreliable as to be undeserving of any weight.

1. Dr. Scott Morton

Complaint Counsel grounded its case primarily on the opinions of Dr. Fiona Scott Morton, an economist. Her opinions are inadmissible, unreliable and/or unsupportive of Complaint Counsel's allegations.

Dr. Scott Morton's opinions on MCED technology, the viability of alternative NGS platforms, regulatory approval, and reimbursement should be disregarded because she lacks the scientific expertise to opine on these matters. It is black letter law that experts must be qualified to offer the opinions that they seek to express. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993); *Nat'l Comm'ns. Ass'n v. AT&T*, 1998 WL 118174, at *42–49 (S.D.N.Y. Mar. 16, 1998) (excluding an economic expert's testimony because he conceded he was not an expert in the technical area where he was offering an opinion). Dr. Scott Morton is not an expert in MCED tests, clinical trials, any field of chemistry or biological studies, or cancer screening technologies, nor is she a biochemist, molecular biologist, pathologist or medical doctor of any kind. (PFF ¶¶ 2065.1–65.2.) Dr. Scott Morton lacks medical training of any kind or direct experience with cancer screening or MCED tests. (PFF ¶ 2065.3.) She lacks any scientific expertise to compare and contrast the features of the Galleri test with other MCED tests in development and lacks the clinical expertise to dispute whether or not it would be improper for a physician to use Galleri as a substitute for another test. (PFF ¶¶ 2065.4–65.5.) *See In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 758 (N.D. Ohio 2014) ("The Court will not permit Bresnahan (or any other economist/damages expert) to offer any opinion suggesting a washer does not have a design defect or has a 'superior design' or is 'innovative.' Bresnahan is not an engineer and has no expertise to render such a conclusion."); *Nat'l Communs. Ass'n*, 1998 WL 118174, at *42–49

(excluding an economic expert's testimony because he conceded he was not an expert in the technical area where he was offering an opinion).

In addition to lacking expertise regarding MCED tests, which in itself should disqualify Dr. Scott Morton from providing her tendered opinion on a MCED test market definition, she has also failed to conduct important quantitative analyses related to market definition. Dr. Scott Morton did not perform a quantitative hypothetical monopolist test, quantitative SSNIP analysis, critical loss analysis, or an analysis of whether a SSNIP for one MCED test would result in switching to another MCED test. ((PFF ¶ 2067.1.) She did not examine data describing past purchase patterns of consumers and their responses to price changes; did not consider any normal course of business documents describing how Galleri customers responded to a price increase; and did not consider any normal course business documents describing how any MCED test customer would respond to a price increase. (PFF ¶ 2067.2.) Dr. Scott Morton did not attempt to fill the information gaps using surveys or other means, including information about the preferences and switching behavior of clinicians, patients, and payors related to the products she includes and excludes from her proposed MCED market, and, most importantly, she did not attempt to analyze substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. (PFF ¶ 708.3.) *See Teradata Corp. v. SAP SE*, 2021 WL 5178828, at *18 (N.D. Cal. Nov. 8, 2021) ("Asker's methodology in defining the tying market is unreliable. Contrary to Teradata's assertion, he does not measure the cross-elasticity of demand or the substitutability of products based on reliable quantitative and qualitative analyses. Because his methodology for defining the relevant tying market is unreliable, his conclusions that SAP has market power in his proposed market should also be excluded."); *Lantec, Inc. v. Novell, Inc.*, 2001 U.S. Dist.

LEXIS 24816, at *14–16 (D. Utah Feb. 13, 2001) ("This is simply insufficient foundation for, or evidence of, the consumer behavior or preferences helpful in defining a relevant market for antitrust purposes. . . . Dr. Beyer's evidence amounts to nothing but anecdotal information from his own experience, that of two IT managers similarly situated, and the experience of one supplier (Lantec) which Dr. Beyer is extrapolating into 'expert evidence.' Lantec has defined the market as 'worldwide,' and the anecdotal evidence cited is statistically insignificant in terms of number and geographic sampling. . . . His conclusions as to the switching costs and therefore the assumed 'lock-in' phenomenon are based on basically the same, and therefore similarly insufficient, foundation.") (citations omitted).

Dr. Scott Morton's opinion as to the related product market is flawed for some of the same reasons that doom her market definition opinion. Dr. Scott Morton lacks expertise on subjects relevant to establishing a related market that consists only of Illumina's next generation sequencers. (PFF ¶¶ 2083–83.6.) By defining the related product market to include only Illumina's sequencers and consumables, Dr. Scott Morton simply assumes that Thermo Fisher, BGI, Oxford Nanopore, Genapsys, Singular Genomic, Ultima Genomics and Roche do not provide NGS platforms or consumables that compete with Illumina's sequencers and consumables. (PFF ¶ 2084.) She ignored or discounted the evidence of investment, development, and market entry of these companies as well as other companies that are developing non-NGS platforms. (PFF ¶¶ 2085–96.) *See, e.g.*, *Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Ca. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted."); *Rimbert*

v. Eli Lilly & Co., 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009); *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

Dr. Scott Morton's conclusion that Illumina allegedly will foreclose competition in the alleged MCED market by raising rivals' costs is based entirely on speculation. Dr. Scott Morton did not analyze the degree to which Illumina would have to raise the prices to GRAIL's putative rivals to effectively foreclose them. (PFF ¶ 2099.2.) Dr. Scott Morton's "model" does not account for any efficiencies, ignoring the statement in the Vertical Guidelines that vertical mergers have the capacity to generate cognizable efficiencies. Vertical Merger Guidelines at 11. And Dr. Scott Morton does not perform a diversion analysis and disregards the testimony of Respondents' two experts who are practicing physicians, Drs. Cote and Abrams, who have testified that number of cancers detected and signal of origin are key differentiating features that will affect physician and patient choice. (PFF ¶¶ 841.10–41.11.) Given these flaws, Dr. Scott Morton's foreclosure analysis is unreliable. *See Teradata Corp.*, 2021 WL 5178828, at *18.

Dr. Scott Morton refused to engage with the substance of the Open Offer and did not analyze whether it can limit Illumina's ability to raise rivals' costs, which is yet another reason to disregard her opinions. But she conceded that the Open Offer provides contractual commitments that did not exist prior to Illumina's announcement of the proposed merger and that absent the Open Offer, customers would not have any protection against price discrimination; would pay different prices for the same Illumina products; would be subject to price changes after the expiration of an operative supply agreement; and would not be guaranteed lower sequencing costs. (PFF ¶¶ 2111, 2116.) She further conceded Illumina's prices for

sequencing could go down by less than the price reduction commitment provided in the Open Offer, and she could not identify any supply agreement in the relevant industries with pricing protections more favorable than those set forth in the Open Offer. (PFF ¶ 2116.) In short, Dr. Scott Morton could not deny that the Open Offer commits Illumina to supporting all customers equally; lowers prices; and puts many oncology customers in a better position than they otherwise would have been prior to the Open Offer. (PFF ¶¶ 2010–16.)

Finally, Dr. Scott Morton's opinions are inadmissible and unreliable to the extent that she impermissibly usurps the role of the fact finder by opining on the credibility of witness testimony or weighing the evidence. For example, she disregarded the consistent testimony of the Illumina and GRAIL witnesses about efficiencies, while taking at face value the self-serving opinions of customer witnesses Complaint Counsel lined up to criticize the deal. "The credibility of witness testimony is a matter left to the [fact finder] and generally is not an appropriate subject for expert testimony." *Wilson v. Muckala*, 303 F.3d 1207, 1218 (10th Cir. 2002); *see also United States v. Adams*, 271 F.3d 1236, 1246 (10th Cir. 2001) ("The offered testimony does little more than vouch for the credibility of another witness and thereby encroaches upon the [fact finder's] vital and exclusive function to make credibility determinations." (internal quotations omitted)). Dr. Scott Morton repeatedly weighs the evidence in the course of offering her opinions here. (PFF ¶ 2136.1.) [redacted] She also takes at face value the FTC's arguments and disregards efficiencies sworn to by Illumina fact witnesses. (PFF ¶ 2136.1.) ("Q. . . . No one has shared with you any deposition testimony concerning

supply chain and operational efficiencies expected because of the transaction; correct? A. I asked for everything important. Therefore, there isn't anything of importance for my report that falls in the category you are talking about, or I would've seen it.").)

2. Dr. Amol Navathe

Complaint Counsel relied on the opinions of Dr. Amol Navathe to (1) address the FDA approval process for diagnostic tests; (2) explain payor coverage decisions for Galleri; and (3) criticize Dr. Carlton's analysis of the value of lives saved from the acceleration of Galleri. Those opinions should be given no weight. To begin, Dr. Navathe lacks the expertise to opine on FDA approval and payor reimbursement. By his own admission, Dr. Navathe has no experience or expertise regarding FDA's PMA approval standards, the typical approval process, or any parts of that process that may be influenced by the novel nature of the Galleri test. (PFF ¶¶ 2140, 2142-43.) Courts routinely disregard expert opinions regarding FDA regulations where the expert's only connection to the FDA is through his experience as a physician. *See, e.g.*, *Hall v. Boston Scientific Corp.*, 2015 WL 868907, at *24 (S.D.W.V. Feb. 27, 2015) (finding that expert's "distinguished career as a urogynecologist cannot uphold his opinions on product warnings and FDA compliance.")

[redacted] (PFF ¶¶ 2141, 2144–49.) Allowing "experts" to testify as to purely subjective views in the guise of expert opinions would "border on the absurd." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 544 (S.D.N.Y. 2004).

Dr. Navathe's contention that that Respondents failed to present sufficient evidence to support Dr. Carlton's analysis of the value of lives saved fails for several reasons. *First*, Dr. Navathe's criticisms of Dr. Carlton's approach are misguided: it is reasonable to use the value of a statistical life (as opposed to the value of life years gained) as it means that one values all lives equally and is the method recommended by the U.S. Government; Dr. Carlton's analysis is not based on a trained data set that biases the result; and the analysis does not apply 22 years of benefit into nine years. (PFF ¶ 1124.5.) Dr. Navathe overlooked the fact that Dr. Carlton's calculation was, if anything, conservative because it did not take into account improvements to Galleri's performance as a result of acceleration—it is likely many more lives will be saved if Illumina succeeds in helping GRAIL accelerate Galleri's market adoption. (PFF ¶¶ 1125–25.3.)

Second, Dr. Navathe did not reach independent conclusions about whether the Transaction will accelerate approval of Galleri. (PFF ¶¶ 2170–76.) Dr. Navathe did not form an independent opinion of the life years that can be saved by acceleration of Galleri. (PFF ¶ 2185.) Nor did he offer any estimate in his report for what the possible economic benefit could be of accelerating the availability of Galleri at a broad scale. (PFF ¶ 2176.1.) Having merely reviewed selected documents provided to him by Complaint Counsel, Dr. Navathe cannot properly testify regarding acceleration. *See Mid-State Fertilizer Co. v. Exch. Nat'l Bank*, 877 F.2d 1333, 1340 (7th Cir. 1989) (excluding economist who merely "examined materials produced in discovery and drew inferences from the record" instead of "draw[ing] on the skills of an economist").

Third, Dr. Navathe's critique usurps the role of the Court insofar as he purports to opine on whether Respondents made a sufficient showing of an efficiency. *See Mid-State*

Fertilizer Co., 877 F.2d at 1340 (excluding economist who merely "examined materials produced in discovery and drew inferences from the record" instead of "draw[ing] on the skills of an economist"); *SEC v. Tourre*, 950 F. Supp. 2d 666, 675, 678, 681-82 (S.D.N.Y. 2013) ("Acting simply as a narrator of the facts does not convey opinions based on an expert's knowledge and expertise; nor is such a narration traceable to a reliable methodology."). Even if Dr. Navathe could appropriately offer such an opinion, he could not do so here because he failed even to assess the entirety of the proof put forward by Respondents. *See, e.g.*, *Abarca*, 761 F. Supp. 2d at 1066 n.60 ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted.").

3. Dr. Dov Rothman

Complaint Counsel relied on the opinions of Dr. Dov Rothman, an economist, for his interpretation of what agency guidelines require to substantiate merger efficiencies and for his opinion as to whether Respondents' experts have substantiated efficiencies regarding (a) accelerated regulatory approval for GRAIL's Galleri test; (b) accelerated payor acceptance of Galleri; (c) innovation collaborations; and (d) cost savings. Like Dr. Navathe's critique of Dr. Carlton, these opinions should be given no weight because they invade the Court's province and constitute improper legal opinion. *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d at 64 ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law.").

The Rothman Report never cites a single economic treatise, study, or authority. Dr. Rothman instead relies exclusively on a standard for substantiating efficiencies that he purports to have distilled from two agency policy guidelines: the Vertical Merger Guidelines of

July 30, 2020; and the Horizontal Merger Guidelines of August 19, 2010 (collectively, the "Guidelines"). [redacted] (PFF ¶ 2190.)

But in his testimony, Dr. Rothman admitted he applied his own standard because the Guidelines do not provide a "definition of reasonable means". (PFF ¶ 2190.1.) There is no evidence that anyone else has accepted, tested, or applied Dr. Rothman's personal method for efficiency substantiation. *See* Fed. R. Evid. 702 (requiring testimony to be "product of reliable principles and methods"). His "I know it when I see it" test has no place here. To the extent that Dr. Rothman intends his interpretations of the Guidelines to guide the ALJ's assessment of what may constitute a cognizable efficiency, his opinions improperly invade the Court's province. *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d at 64.

By his own admission, Dr. Rothman lacks the expertise to opine on efficiencies related to the acceleration of Galleri's FDA approval and payor reimbursement and any of his opinions on these topics should also be given no weight. (PFF ¶¶ 2194–94.7.) Dr. Rothman's two remaining conclusions relate to Respondents' expert evidence regarding efficiencies of medical breakthroughs from combining Illumina's and GRAIL's research capabilities, and cost savings from combining supply chain and laboratory resources. [redacted] However, Dr. Rothman did not conduct a study of record evidence to determine whether support for any efficiency existed and he did not analyze all of the evidence considered in Respondents'

expert reports. (PFF ¶ 2200.) His artificially limited inquiry to only materials he characterizes as specifically "offered as substantiation," makes his opinions irrelevant and unreliable. *See In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425, 437–38 (excluding experts that "ignored a large amount of information").

D. The Alleged Other MCED Developers.

In addition to its three experts, Complaint Counsel relies on the testimony of representatives of the companies allegedly developing MCED tests they hope will one day rival GRAIL. Rather than further Complaint Counsel's cause, this testimony underscores the fact that Galleri is very different from the MCED tests-in-development and that they can survive without the assistance of Illumina.

[redacted]

Not only are the purported MCED tests in development far from launching, but by the third parties' own admission, they will likely be complementary to Galleri. [redacted]

[redacted]; (PFF ¶ 1807.1 ("Guardant360 CDx is approved for a single-site use, which does not require us to use diagnostic instrument capability, and so we're able to submit that application for single-site use independent of Illumina.").)

Insofar as other MCED test developers expressed concern that the Transaction will hurt them, the testimony deserves little weight because they have an incentive to prevent the acquisition. Many of these test developers admit that they consider Galleri to be their primary, if not sole, competition. [redacted]; (PFF ¶ 1831 (Mr. Getty testifying that Guardant considers GRAIL a competitor).) Documents produced in the case also show that these purported MCED developers had a motive to block the deal. [redacted]

[redacted]

Simply put, Exact (and all the other putative MCED test developers) believe it is in their interest to block this procompetitive merger because they know it will make GRAIL more competitive and accelerate Galleri reaching commercial scale.

Exact's motives to block the transaction deserve particular scrutiny. Exact believes they can prevent the reunification of Illumina and GRAIL if they object vigorously enough, even if those objections are commercial concerns masquerading as competition concerns. A closer look at the circumstances surrounding Exact's acquisition of Thrive show that Exact has not acted in good faith, both in its representations in this proceeding and in its dealings with Illumina.

[redacted]

After Illumina announced its agreement to reacquire GRAIL, Exact entered into an agreement to acquire Thrive for $2.1 billion. (PFF ¶ 929.1.) Apparently, Exact had no concerns spending $2.1 billion to buy Thrive knowing full well that Illumina was reacquiring GRAIL. [redacted]

[redacted]

Once the Exact/Thrive merger closed in January 2021, Exact did a complete about face. Exact thought they had an advantageous situation and began making demands of Illumina for below-cost pricing and access to GRAIL intellectual property. (PFF ¶¶ 1073.5.) [redacted] Exact and Thrive's own documents tell a different story. [redacted]

Exact's claim that its $2.1 billion acquisition is dependent on obtaining below-cost pricing from Illumina either means that Exact has misled this Court and Illumina or demonstrates a shocking level of negligence in its due diligence of Thrive. Acceleration will save lives, but in Mr. Conroy's estimation, it will make it harder to justify their $2.1 billion acquisition, which Exact made knowing full well that Illumina was buying GRAIL. Exact sees the acceleration of Galleri as a commercial threat to CancerSEEK. They do not want competition on the merits. They are putting their own profits above patient welfare and saving lives.

There also is good reason to cast doubt on Natera's claims regarding its putative MCED test and past dealings with Illumina. Natera is a defendant in multiple lawsuits accusing Natera of dishonesty. For example, Natera has been accused by Progenity of engaging in a "campaign to seek retribution against Progenity for rejecting Natera's technology six years ago and developing its own superior technology that competes with Natera." (PFF ¶ 1881.) Guardant has accused Natera of making false comparisons of its MRD test to Guardant's MRD test "[w]ith little or no concern for the [colorectal cancer] patients who could be harmed". (PFF ¶ 1881.1.) CareDx, a rival to Natera in kidney transplant testing, has accused Natera of "making various false and misleading claims that [Natera's test] is superior to CareDx's AlloSure" kidney transplant test". (PFF ¶ 1881.1.) [redacted]

Furthermore, while a number of the purported MCED developers expressed skepticism regarding the Open Offer, none fully understood or accurately described it. Several

of the MCED test developers admitted that they had not reviewed the Open Offer at all and thus could not reliably testify to Illumina's ability to foreclose GRAIL's rivals. (*See, e.g.*, PFF ¶ 1073 (Conroy (Exact/Thrive) Tr. 1725–27 ("Q. So you haven't read the open offer, right? A. That's what I just testified to.")); PFF ¶ 1895 (Gao (Singlera) Tr. 2952 ("Q. And are you aware that that open offer was amended as of just last week to make certain improvements to it? A. Sir, to be frank, I am not even aware of the first open -- open offer until my lawyer told me, and I am not even aware of the one if you don't tell me a week ago.").)

E. IH Transcripts and Other Documents.

Finally, Complaint Counsel relies on a collection of documents that are inadmissible and unreliable. Over Respondents' objections, Complaint Counsel offered (and the Court admitted into evidence) the IH transcripts of 34 witnesses. The IH testimony should be given no weight because it would violate Respondents' right to cross examine and present evidence. Respondents were not present at the IHs of third parties and therefore had no meaningful opportunity to cross-examine. *See TK-7 Corp. v. Est. of Barbouti*, 993 F.2d 722, 732 (10th Cir. 1993) ("[T]he absence of an opportunity to cross-examine the source of the hearsay information renders it unreliable".) While Respondents were present at the IHs of their own witnesses, they had no real ability to object to improper questions or cross-examine. For example, Complaint Counsel refused to allow Respondents' counsel to ask clarifying questions during Mr. deSouza's IH testimony. (PFF ¶ 1221.) Despite not allowing Respondents to clarify Mr. deSouza's testimony, Complaint Counsel later attempted (unsuccessfully) to impeach Mr. deSouza at trial with the very IH testimony Respondents sought to clarify at the IH. (PFF ¶ 1221) ("Q. And do you recall that at the time of your investigational hearing on March 24th of this year, you were not aware of any synergies? A. That's not correct. We spoke a lot in that hearing about synergies, and then there was one section of the investigational hearing where we

were talking about a specific page that had work streams, and then that's when I said I wasn't aware of the synergies associated with that work stream, but we talked in that investigational hearing a lot about the synergies before that -- before that part and after that part, too, and then we talked a lot about the synergies in the deposition, too. So the part of the investigational hearing where we talked about -- where I said I was not aware of the synergies, I was talking about the output[31] from that specific, you know, work team that you were showing me on that page.").)

Furthermore, IH testimony constitutes inadmissible hearsay because: (1) it is not necessary to "aid in the determination of the matter" as Complaint Counsel could and did take deposition testimony from most of the nonparties represented in the IHTs; and (2) the IHTs are not "reliable" or "fair", as they are replete with improper leading questions, speculation and inadmissible lay opinion. *See In re Resort Car Rental Sys., Inc.*, 83 FTC 234, 1973 WL 165056, at *33 (July 31, 1973) ("Complaint counsel made a request . . . to introduce into evidence excerpts of testimony attained at an investigational hearing, for the truth of the matters contained therein. The administrative law judge rejected this evidence . . . .").

VII. COMPLAINT COUNSEL IS NOT ENTITLED TO THE REMEDY IT SEEKS

As explained above, Complaint Counsel has failed to carry its burden to show that this life-saving Transaction is unlawful. As such, no remedy is appropriate in this case. But

[31] The IH testimony of third parties was wasteful and cumulative in light of the fact that the court also admitted deposition testimony and trial testimony, and vastly expanded Complaint Counsel's effective trial time. *See In re McWane*, No. 9351, 2012 WL 3597376 (FTC Aug. 15, 2012).

even if that were not the case, Complaint Counsel's request for a divestiture is overbroad, against the public interest and inequitable. Accordingly, it should be denied.[32]

First, a divestiture remedy would be overbroad and unnecessarily punitive. The purpose of an antitrust remedy is to "restore competition". *United States* v. *E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 326 (1961). "Courts are not authorized in civil proceedings to punish . . . and relief must not be punitive." *Id.* The idea is to "attempt to craft a remedy that will create a competitive environment that would have existed in the absence of the violations." *In re Evanston Nw. Healthcare Corp.*, No. 9315, 2007 WL 2286195, at *77 (F.T.C. Aug. 6, 2007). "Absent some measure of confidence that there has been an actual loss to competition that needs to be restored, wisdom counsels against adopting radical structural relief.'" *New York* v. *Deutsche Telekom AG*, 439 F. Supp. 3d 179, 230 n.23 (S.D.N.Y. 2020) (quoting *United States* v. *Microsoft Corp.*, 253 F.3d 34, 80 (D.C. Cir. 2001)).

A divestiture order would be unnecessarily punitive, eliminating the life-saving benefits of the Transaction in order to address concerns that are entirely eliminated by the Open Offer. (*See* Section III.) As explained in detail in Section III, Illumina's Open Offer eliminates all of the alleged concerns raised by Complaint Counsel. Illumina has committed to formalize these binding contractual commitments in a consent order. A Commission consent order requiring Illumina to abide by the terms of the Open Offer would be a more appropriate and effective remedy than divestiture. A consent order would allow the combined company to continue pursuing its plan to save more lives, more quickly. *See AT&T,* 916 F.3d at 1041 (noting

[32] The Complaint filed in this case states that the Commission may order a number of remedies. (Compl. at 28.) It is not clear which (if any) of these remedies Complaint Counsel is seeking. Respondents reserve the right to respond to any remedy proposed by Complaint Counsel in its opening post-trial brief.

that the government has recognized, "especially in vertical mergers, that conduct remedies . . . can be a very useful tool to address the competitive problems while preserving competition and allowing efficiencies that may result from the transaction"). As explained in Section IV above, the Transaction will accelerate Galleri's widespread adoption and save lives. A divestiture would prevent these benefits from being realized.

Second, divestiture of GRAIL would result in harm to "the interest of the general public." *United States* v. *Am. Tobacco Co*., 221 U.S. 106, 185 (1911). Where divestiture will result in the elimination of benefits that have been created by a merger, an alternative remedy is appropriate. In *Evanston*, Complaint Counsel sought the divestiture of respondent's acquisition of Highland Park Hospital and Chief Administrative Law Judge McGuire agreed. The Commission reversed Judge McGuire's divestiture order and instead entered an injunctive remedy. *In the Matter of Evanston Nw. Healthcare Corp.,* No. 9315, 2007 WL 2286195 (F.T.C. Aug. 6, 2007) (requiring respondent to provide a non-divestiture proposal to the Commission for relief that would remedy the alleged harm). In reaching its decision, the Commission noted that respondent had "made improvements at Highland Park since the merger." *In re Evanston*, 2007 WL 2286195, at *78. The improvements were "relevant to determining whether divestiture is appropriate because divestiture may reduce or eliminate the resulting benefits for a material period of time." *Id.*

As explained above, if the Transaction is allowed to proceed, it will result in significant efficiencies, including the saving of thousands of lives, the acceleration of Galleri, significant cost savings and R&D efficiencies. A divestiture would eliminate all of these efficiencies at great loss to the public interest.

But even assuming these efficiencies are discounted, a divestiture will remove the undisputed financial security that the Transaction has brought to GRAIL. Despite its tremendous progress to date, GRAIL faces many challenges which will require significant funding. For example, it is undisputed that continuing the population-scale clinical trials that GRAIL and now Illumina have undertaken to date will cost millions, if not hundreds of millions of dollars. (PFF ¶ 2129 (PX7138 (Scott Morton Trial Dep. at 319).)) Similarly, as Respondents have described above, Illumina will need to spend millions of dollars to accelerate Galleri's FDA approval and achieve widespread payor reimbursement for Galleri. The Transaction has provided GRAIL with critical funding that it needs in order to achieve these goals. (*See, e.g.*, PFF ¶ 1629.1 (Freidin (GRAIL) Tr. 3000 ("We knew that we would have to go out and to raise a significant amount of capital and more than -- and more than once over the, you know, next five or six years, and so by Illumina acquiring us, you know, we don't have to worry about that anymore. Illumina is a, you know, multibillion-dollar, profitable business that generates cash flows. And if they ever ran out of cash flows or we needed to spend more, they have successfully raised debt and done other offerings, so it -- in my view, it derisked our capital needs and accelerated our ability to put capital to work immediately and was another positive benefit of the acquisition."); PFF ¶ 1141.5 (Bishop (GRAIL) Tr. 1416 ("ongoing access to funding is more secure as part of a large, successful, profitable company, and I believe that Illumina, as an outstanding technical innovation company, deeply understand the importance of ongoing investment in research and development. That's how they've been successful, by continuing to do that. So I believe that the resources that we need to be reliably continuing to make those sorts of investments are greatly secured.").)

Without the investment from Illumina and if GRAIL is forced to, once again, seek funding, not only will Galleri's approval and widespread payor reimbursement not be accelerated, but also it is likely to be slowed down compared to the pre-Transaction status quo. [redacted] Unwinding the deal in its entirety would also distract GRAIL's personnel. The result will harm the public interest.

Third, under the unique circumstances of this case, divestiture would be fundamentally inequitable to Respondents. Divestiture is an equitable remedy, *E. I. du Pont de Nemours & Co.*, 366 U.S. at 326, and "the current situation is always relevant to the question of equitable relief," Areeda & Hovenkamp, *Antitrust Law* ¶ 1205a. "Economic hardship" to Respondents is appropriately considered when choosing among "effective remedies", and the Supreme Court has long held that a remedy must take "proper regard for the vast interests of private property which may have become vested in [for example, stockholders] as a result of the acquisition . . . without any guilty knowledge or intent." *du Pont*, 366 U.S. at 327–28.

Here, it is undisputed that a divestiture would affect private property interests. Indeed, attempting to reverse this billion dollar Transaction would be a significant undertaking. More important, allowing the Commission to order a divestiture after it withdrew its complaint seeking a preliminary injunction in federal court would be inequitable. At the outset of this case, Respondents agreed not to close the Transaction while the Commission's preliminary injunction complaint was adjudicated by a federal court. The Commission later withdrew its preliminary injunction and allowed the Transaction to close under U.S. law. It would be fundamentally

unfair for the Commission to order a divestiture of a Transaction it affirmatively decided not to prevent. This is especially the case where, as here, there are narrower and less costly remedies available.

CONCLUSION

In asking the Court to undo the Transaction despite these flaws in its case, Complaint Counsel asks the Court to do what no court ever has. It asks the Court to scuttle a vertical merger where the supposed relevant market is at best undefined and at worst comprised of products that, save one (Galleri), are pre-commercial, may never launch and have none of Galleri's distinguishing features; where Complaint Counsel does not even profess to have defined a related product market; where no economic model shows that the alleged anticompetitive effects of the Transaction outweigh its benefits; where Complaint Counsel offered no evidence to prove material diversion, and in fact there has not been a single sale – ever – of the products whose sales will allegedly be interrupted; where the alleged foreclosure strategy could not benefit the upstream firm for years (as GRAIL is not even supposed to become profitable until 2026), but foreclosing GRAIL's putative rivals would have an immediate, adverse impact on Illumina's sales and reputation; where the cost of the upstream product will be a very small part of downstream revenues going forward; where there is on-going investment and entry in the upstream market, whereas there will not be meaningful entry in the downstream market for years; where the only other vertical transaction involving the upstream firm was followed by a period of increased (not decreased) competition; where the upstream firm made a binding, long-term commitment making it impossible (absent severe penalties) to raise rivals' costs ; and where the Transaction will result in substantial, merger-specific efficiencies.

For these reasons, and as further discussed in Respondents' Proposed Findings of Fact and Conclusions of Law (submitted herewith), Complaint Counsel's attempt to unwind the

reunion of Illumina and GRAIL should be rejected and judgment should be entered in favor of Respondents.

Dated: April 15, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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I also certify that I caused the foregoing document to be served via email to:

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